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KATHARINE F. TREVES BSc Hons Dip Clin Psy

The management of insomnia  
on a residential pain management programme:  
A single case series and qualitative analysis.

A thesis submitted in partial fulfilment of the requirements of the Open University for the  
degree of Doctor of Clinical Psychology

JUNE 1999

SALOMONS  
CANTERBURY CHRIST CHURCH UNIVERSITY COLLEGE

AWARD DATE: 29 JUNE 1999

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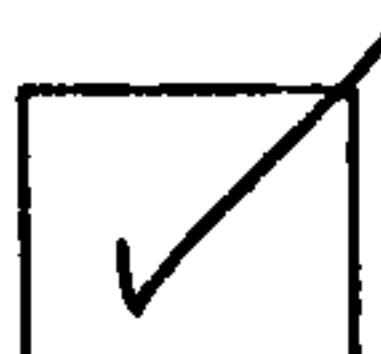
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## INTRODUCTION

Insomnia, 'the subjective inability to obtain adequate sleep' (Gillin & Byerley, 1990), is a widespread and debilitating complaint (Lacks & Morin, 1992). Epidemiological data in both the UK and USA estimate that at least 30 per cent of adults report at least occasional difficulties in falling asleep or staying asleep, including up to 17 per cent for whom insomnia is persistent and troublesome (Shapiro & Dement, 1993; Gallup Organisation, 1991). The condition not only causes distress and unhappiness to the individual concerned, nor are its consequences confined to the night-time: it can significantly affect marital and family relationships, and the individual's day-time cognitive performance may be compromised too (Horne, 1988; Coyle, 1998). Insomnia may also have serious economic consequences: road traffic and industrial accidents are frequently linked to sleep loss, as are reduced productivity and increased absenteeism (National Commission on Sleep Disorders Research, 1993).

Whilst the prevalence of insomnia is high in the general population, it is a significantly more common problem in those individuals experiencing chronic pain, usually defined as pain which persists beyond the usual healing time, typically taken to be a maximum of six months (International Association for the Study of Pain, 1986). Seventy per cent of patients attending an out-patient pain clinic were found by Pilowsky, Crettenden & Townley (1985) to describe their sleep as 'poor' rather than 'good' or 'fair', and using objective measures of sleep, Lavic, Epstein, Tzischinsky, Gilad, Nahir, Lorber & Scharf (1992) found the sleep of a sample of 13 women with active Rheumatoid Arthritis significantly poorer than a control group of healthy women, and closely associated with the degree of pain experienced.



The significance of the problem within chronic pain is underscored by studies assessing the degree of sleep disturbance in this population. In a sample of 40 patients with chronic musculoskeletal pain diagnosed as suffering from insomnia, Wilson, Watson & Currie (1998) found relatively low mean total sleep times of 4.9-5.9 hours, sleep disrupted by frequent awakenings and low mean sleep efficiency values of 65-76 per cent (85% per cent is the cut-off typically used to define good sleepers; Frankel, Coursey, Buchbinger & Snyder, 1976). Studies have consistently found a correlation between the degree of sleep impairment and level of depressive symptomatology in chronic pain (Haythornthwaite, Hegel & Kerns, 1991; Affleck, Urrows, Tennen, Higgins & Abeles, 1996) and whilst it is not clear whether depression is a cause or a result of insomnia (Morin & Ware, 1996), there is certainly no reason to believe that the consequences of poor sleep are any less severe in this population than in those who are pain free.

In contrast to the number of studies generated on trying to understand and develop effective treatments for people with insomnia without concomitant pain, the amount of work carried out in examining the difficulties for people with chronic pain conditions who are having difficulties in sleeping, and aiming to develop effective means of alleviating their distress, has been shamefully sparse. This area will be the focus of the current study, but before reviewing the few studies which have been carried out on insomnia and chronic pain, it is important to be familiar with the classification, assessment, intervention and research issues of insomnia work in general. This is covered in the following sections:

### **1.1 Classification and Assessment**

The International Classification of Sleep Disorders (American Sleep Disorders Association,

1990), subdivides the most common form of insomnia, disorders in initiating and maintaining sleep, into three categories: *initial insomnia* (difficulty in falling asleep), *sleep maintenance insomnia* (difficulty in maintaining sleep) and *terminal insomnia* (early morning waking). These divisions are not adopted by the most recent edition of the Diagnostic and Statistical Manual for Mental Disorders (DSM IV) (American Psychiatric Association, 1994) but are widely referred to in the literature, and used in assessing the differential outcome of treatments for different types of insomnia. DSM IV is, however, careful to distinguish sleep disturbance arising as a result of a general medical condition from disruption of sleep without apparent psychopathological or medical cause (*primary insomnia*).

Since insomnia is typically defined by self report, it would seem crucial in normal clinical situations that any assessment of the condition focusses on the individual's perception of their sleep. After the clinical interview, therefore, the most frequently used forms of assessment in clinical settings are self-report measures, such as sleep questionnaires and diaries. These usually include measures of sleep latency (time taken to fall asleep), awakenings (number of awakenings when it was difficult to return to sleep), sleep efficiency (ratio of time spent asleep to time spent in bed) and sleep duration. However, other important parameters include quality of sleep (enjoyment, depth) and daytime functioning (feeling refreshed on waking, fatigue during the day), both of which are best examined by self-report measures.

The self-report daily sleep diary is the most practical, economical, and widely used method for assessing sleep (Bootzin & Engle-Friedman, 1981; Lacks & Morin, 1992). Although insomniacs usually over-estimate sleep latency and underestimate total sleep time in comparison with electroencephalographic measures, their self-reports are consistent and thus



provide a valid and reliable measure of insomnia (Coates, Killen, George, Silverman, Marchini & Thoreson, 1982). They do, however, have the disadvantage of being rather burdensome to complete. Retrospective sleep questionnaires are usually used as an adjunct to more detailed measures of sleep because where treatment is anticipated, they are subject to reporting bias in the direction of exaggerating sleep disruption (Bootzin & Engle-Friedman, 1981).

In specialist clinics, nocturnal polysomnography is recognised as the “gold standard” for the measurement of sleep and the diagnosis of sleep related conditions (Lacks & Morin, 1992), but suffers from problems of high cost and reactivity to the laboratory situation (Lichstein & Riedel, 1994). Other less costly and home based methods of objective assessment (e.g. Sleep Assessment Device, Kelley & Lichstein, 1980; actigraphy, Wilson *et al.* 1998; bed partner report) have been used to corroborate self-report measures but like polysomnography, these forms of assessment do not elicit patients’ perspectives of their sleep. Treatment success, when defined by the patient, is more dependent on *their* account of changes in the quality and quantity of their sleep, than on changes in externally measured parameters.

## **1.2 Pharmacological Treatment**

The most common form of treatment for insomnia is pharmacological therapy. About 14 million prescriptions for hypnotics were written in the UK in 1989, in spite of the evidence that most sleeping tablets have little beneficial effect on sleep after a few weeks of treatment (Committee for the Review of Medicines, 1980), and that they can result in problems of day time residual effects, tolerance, dependence and rebound insomnia (Hindmarch, 1991; Morin & Kwentus, 1988; Rochrs, Vogel & Roth, 1990). They are now becoming less available, partly as a result of the withdrawal of some products from the market, and partly because prescribers

have begun to take on the message that they are inappropriate for chronic sleep disturbance (Committee on the Safety of Medicines, 1988; Espie, 1994; Pathare & Paton, 1997).

Benzodiazepines are also prescribed to people with insomnia secondary to chronic pain (and are no less likely to result in similar problems). Clinical observation, however, suggests that physicians are more likely to respond to the complaint of sleeping problems in the chronic pain patient by prescribing tricyclic antidepressants, usually a low dose of amitriptyline taken at night. The supposed analgesic effect of a low dose of antidepressant drugs in chronic pain remains the subject of dispute (Goodkin, Vrancken & Feaster, 1995) but their sedative effect is clearly recognised, and it is this that has led to the recommendation of prescribing them as a means of alleviating insomnia in patients with chronic pain (Mitler, Poceta, Menn & Erman, 1991; Turner & Denny, 1993).

### **1.3 Psychological Interventions**

Recognition of the limitations and dangers of long-term use of benzodiazepines, in addition to increasing acknowledgment of the role of psychological factors in maintaining sleep disturbance (Lacks, 1987; Espie, 1991), has led to the development of a range of non-pharmacological treatments for insomnia, based on cognitive and behavioural theories. The first randomised controlled trial comparing these two forms of intervention has recently shown cognitive behavioural therapy to produce more sustained improvements in sleep than pharmacological treatment (Morin, Colecchi, Stone, Sood & Brink, 1999). The following section aims to describe briefly the current most popular psychological treatments for insomnia, with reference to the theory or empirical evidence on which they are based, and to outline some of the research concerning their comparative efficacy:



**Relaxation.** Relaxation-based interventions were originally applied in this field because it was thought that poor sleepers were physiologically over-aroused (Monroe, 1967). The arousal theory has received little support from empirical evidence, however, and it is now thought that the mechanisms at work in relaxation are more likely to be cognitive (Espie, Brooks & Lindsay, 1989). Relaxation has been found to be particularly effective in reducing initial insomnia (Morin, Culbert & Schwartz, 1994), and attention focussing procedures (e.g. guided imagery), which target cognitive arousal, have been found to be superior to somatic forms of relaxation (e.g. progressive muscular relaxation) (Woolfolk & McNulty, 1983; National Institute of Health Technology Assessment Panel, 1996).

**Stimulus Control.** Stimulus control treatment arose from the behavioural analysis of sleep behaviour (Bootzin, 1972). Insomnia is thought to be related to individuals developing a conditioned arousal to their bed and bed-time, as a result of engaging in other activities (e.g. reading, worrying) in bed. Treatment therefore aims to strengthen the bed as a cue for sleep by discouraging its use for any other purpose (excluding sexual activity) and minimising the amount of time spent in bed not sleeping. The procedure has received considerable support in the literature but some uncertainty remains regarding the precise mechanisms responsible for its efficacy (Hauri, 1989).

Stimulus control usually also includes advice on good sleep hygiene i.e. sleep habits and practices known from research to be conducive to good sleep (Hauri, 1977). This typically includes advice on pre-sleep activities (avoiding alcohol, caffeine and vigorous exercise), information about sleep (how much is required), and the sleep environment (comfort of bed and bedroom). Poor sleepers have been shown to have more knowledge of good sleep hygiene

than good sleepers, but they are less likely to put it into practice (Lacks & Rotert, 1986). Although the importance of promoting good sleep hygiene is recognised, evidence suggests that this alone is rarely sufficient to alleviate insomnia (Schocket, Bartelson & Lacks, 1988; Morin *et al.*, 1994).

Since its introduction in 1972, there has been consistent and strong evidence for the efficacy of stimulus control in alleviating both sleep onset and sleep maintenance insomnia, and in studies where it has been directly compared with other strategies, it has been found to yield superior results (Lichstein & Fischer, 1985; Lacks & Morin, 1992; Morin *et al.*, 1994). However, caution is recommended in viewing stimulus control as the 'best' treatment for insomnia; the differences that have been demonstrated between treatments have often been marginal (Murtagh & Greenwood, 1995; Lichstein & Riedel, 1994).

**Sleep Restriction.** The newest approach to insomnia treatment consists of limiting a patient's time in bed. The researchers responsible for its development (Spielman, Saskin & Thorpy, 1987) suggest that although insomnia may be initially caused by a variety of factors, even once these are resolved, it is maintained by the individual spending excessive time in bed in an attempt to obtain more sleep. Over time, the resulting frustration and worry about not sleeping are said to perpetuate the sleeping difficulties further. Treatment therefore involves markedly restricting the amount of time spent in bed, followed by extension of this time contingent upon improved sleep efficiency:

Heralded as "one of the most promising new behavioural treatments of insomnia" (Lilie & Rosenberg, 1990, pp.166), sleep restriction has been shown to be effective in improving both

initial and maintenance insomnia (Spielman *et al.*, 1987). It is still a relatively new treatment, however, and problems of compliance with treatment instructions may be an issue: in the original study by Spielman *et al.* (1987) 16 per cent of participants experienced such difficulty in implementing the procedures that they failed to continue with treatment.

**Cognitive Behaviour Therapy (CBT).** The accumulated evidence from empirical studies that cognitive *arousal* is an important determinant of insomnia (e.g. Gross & Borkovec, 1982; Watts, Coyle & East, 1994) has given rise to a range of cognitively based interventions (e.g. paradoxical intention, articulatory suppression). Another strand of enquiry has been on the important role played by attributions and self-efficacy (Storms & Nisbett, 1970; Killen & Coates, 1979). The cognitive approach most frequently reported in recent studies is based on the theory that dysfunctional cognitions about sleep are responsible for the cause and maintenance of sleep disturbance (Morin, 1993; Sloan, Hauri, Bootzin, Morin & Shapiro, 1993). CBT for insomnia proceeds in the same manner as would CBT for anxiety or depression; cognitive distortions (e.g. "I must have eight hours of sleep every night") are identified, challenged, and replaced by more accurate and helpful beliefs.

A number of recent studies have shown CBT to be highly effective in alleviating insomnia (Lichstein & Riedel, 1994) but the majority of these combine cognitive approaches with other strategies, such as stimulus control and sleep restriction. Additionally, (and probably consequently) the approach is not included in several recent reviews and meta-analyses (Morin *et al.*, 1994; Murtagh & Greenwood, 1995; NIH Technology Assessment Panel, 1996). It is therefore difficult at present to evaluate the independent contribution of CBT to insomnia treatment.



## **1.4 Overview and Future Directions**

After three decades of research into the efficacy of psychological treatments for primary insomnia, clinicians and researchers are now able to prioritise areas for future exploration in which research has so far been deficient. A number of important clinical and research issues has been highlighted by authors reviewing the field (Lacks & Morin, 1992; Chambers, 1992; Murtagh & Greenwood, 1995; NII Technology Assessment Panel, 1996), and the most salient of these are summarised below:

**Individualised Treatment.** In almost all insomnia outcome studies, the therapies being studied have been applied in a standard fashion to randomly assigned participants. Authors have been unanimous in their calls for the tailoring of treatment plans to match the aetiology of each presenting case, and the needs, preferences and circumstances of the client (e.g. Morin & Kwentus, 1988; Hauri, 1991; Chambers, 1992; Lacks & Morin, 1992).

**A Multi-Component Approach.** Rather than viewing insomnia as a condition caused by one particular factor alone, that calls for one specific treatment strategy, another perspective sees insomnia as “almost always the result of many different causes which, taken together, produce the disorder” (Nino-Murcia & Keenan, 1988, pp.102). This view has resulted in the promotion of multi-component interventions, which typically combine stimulus control, sleep restriction and cognitive therapy approaches. They have been found to be at least equally effective as single component therapies (Murtagh & Greenwood, 1995).

**Clinical Significance of Results.** The majority of studies have used group controlled designs.

Whilst findings from these studies have been statistically significant, it is questioned whether



the magnitude of improvements in sleep onset and sleep duration are clinically meaningful to individual patients. The clinical significance of results has been assessed in a minority of studies (Espie, Lindsay, Brooks, Hood & Turvey, 1989; Lacks & Powlishta, 1989; Morawetz, 1989; Morin, Stone, McDonald & Jones, 1994), but has been neglected as an issue in most.

**Use of qualitative methods.** The qualitative approach is built upon phenomenology, a philosophical movement concerned with the study of phenomena: “that which appear real to the senses, regardless of whether their underlying existence is proved real or their nature understood” (Morris, 1981). In contrast with the quantitative approach, which is grounded in the scientific ideals of objective measurement, the main aim of the qualitative approach is to produce explanations of the person’s *experiences* and *actions* in terms of *purposes* and *meanings*, usually in the form of a descriptive narrative or lists of themes or defining features. They allow in-depth study of the meaning of the phenomena to an individual and more complex aspects of individuals’ experiences to be examined.

Research in insomnia to date has been exclusively quantitative. As one of three significant issues prioritised for future outcome research and applications, the NIH Technology Assessment Panel (1996) review of behavioural treatments for insomnia and chronic pain states that “*qualitative* research is needed to help determine patients’ experiences with both insomnia and chronic pain and their treatments” (pp.317).

**Other Populations.** Individuals most at risk of sleep disturbance (i.e. children, older adults, medical and psychiatric patients), have traditionally been excluded from studies on the efficacy of interventions for insomnia because they were not thought likely to benefit from behavioural

therapies. Although a few studies evaluating the efficacy of interventions for insomnia in these populations have now been carried out, and yielded positive results (e.g. Minde, Faucon & Falkner, 1994; Morin, *et al.*, 1999; Stam & Bultz, 1986; Tan, Kales, Kales, Martin, Mann & Soldatos, 1987), a broader scope of investigation is still called for, which specifically targets those populations at high risk of insomnia.

With regards to the chronic pain population, as mentioned previously, this population is one of those at high risk for developing insomnia. Although the experience of constant pain is clearly an important factor, remarkably little is known about the mechanisms responsible for the extent of sleep disturbance in these individuals, their experiences of poor sleep, and for the same reasons as outlined in the section above, they have typically been excluded from insomnia outcome studies, and hence little research has been carried out in evaluating the efficacy of psychological interventions for sleep disturbance in this population. The following section aims to review some of the research which has been carried out in this area, first outlining current understanding and management of chronic pain:

### **1.5 Management of Chronic Pain**

A recent review of the literature yielded a median point prevalence of chronic pain of 15 per cent in the adult population of the western world (Verhaak, Kerssens, Dekker, Sorbi & Bensing (1998). Some chronic pain cannot, by definition, be relieved by existing medical procedures and physical techniques (Williams, 1993a). Whilst some sufferers do not complain of significant deterioration in their quality of life as a result, others develop a disabled state characterised by difficulty in coping with the ongoing pain, and associated psychological and social problems (Jensen, Turner, Romano & Karoly, 1991). Cognitive behavioural

understanding of chronic pain recognises the role of maladaptive beliefs and behaviours in mediating these responses (IASP, 1997), some of which arise from the attempts by the patient and others to alleviate the pain (Williams, 1993a).

In both the UK and USA, the cognitive behavioural model of chronic pain is applied in pain management programmes (PMPs), where the alleviation of pain is not the primary aim, but the improvement of quality of life, despite pain (Williams, 1993a; Linton, 1994). These programmes are usually run by an interdisciplinary team and typical components include stretch and exercise, goal setting, pacing, relaxation, medication reduction and cognitive therapy (Williams, 1993a). PMPs are now widely accepted to be the current treatment of choice in chronic pain once all other standard medical treatments to alleviate pain have been exhausted, and their efficacy in reducing patient distress and disability has been convincingly demonstrated (Flor, Fydrich & Turk, 1992; Morley, Eccleston & Williams, 1999).

## **1.6 Theoretical Explanations**

Although the number of studies conducted into this area is small, researchers have made suggestions about the possible mechanisms responsible for the high prevalence of insomnia in this population:

**The Role of Medical Illness.** Mitler *et al.* (1991) describe three ways in which medical illness may produce disturbance of sleep: firstly, the symptoms of the disorder may be sufficiently disturbing to arouse the patient and prevent the continuous relaxation necessary for sleep; secondly, therapies used to treat the illness may constitute iatrogenic factors leading to insomnia (e.g. long-term use of opioids (DSM IV, 1994); and thirdly, underlying medical



conditions may be exacerbated by sleep or by sleeping in the recumbent position.

Although the medical condition may have triggered the insomnia, Hyypä & Kronholm (1989) conclude that “organic disease *per se* does not explain the high prevalence of sleep complaints in sick people”(pp. 638). Mitler *et al.* (1991) state that “all insomnias can be complicated by and/or propagated by conditioning factors, even after the primary causes have abated”(pp.223). The exploration of the role of other factors would therefore seem to be warranted.

**Sleep Deprivation.** Participants in sleep deprivation studies have been found to have decreased pain thresholds (Johnson, 1969). It is suggested by Wittig, Zorick, Blumer, Heilbronn & Roth (1982) that the poor sleep described by many chronic pain patients may lead to sleep deprivation, which in turn may increase the intensity of pain they are experiencing. In their studies on fibromyalgia, Moldofsky, Scarisbrick, England & Smythe (1975), extend this hypothesis to include the role of emotional arousal. They propose the existence of a vicious cycle in which sleep disturbance arising from a traumatic event (e.g. acute injury), leads to an increase in both musculoskeletal pain and affective disturbance (e.g. depression, irritability or anxiety). These factors are said to exacerbate the experience of pain, and therefore further increase sleep problems.

This model has been supported by evidence from studies in which healthy participants deprived of sleep were found to develop musculoskeletal and mood symptoms said to mimic those of people with fibromyalgia (Moldofsky *et al.*, 1975; Moldofsky & Scarisbrick, 1976). However, methodological weaknesses are apparent in empirical tests of this model: the samples used were small (less than six) and consisted of young, almost exclusively male, college students; affective



disturbance was mainly assessed by investigator observation; and it is noted that the results are not replicated in physically fit individuals.

**Unhelpful Patterns of Behaviour.** Patients with chronic pain often develop ways of behaving in an attempt to cope with their pain, which probably place them at a higher risk for developing insomnia. For instance, fear of causing further damage frequently leads to reduction of activity and hence overall physical deconditioning. The profound effects of inactivity on the body's physiology are described by Harding, Simmons & Watson (1998), and whilst the experimental evidence for a positive effect of exercise on sleep is generally sparse and conflicting (Horne, 1981; Trinder, 1988), a recent randomised controlled trial on older adults (Singh, Clements & Fiatarone, 1997) clearly demonstrated the benefits of increased exercise on sleep.

Morin, Kowatch & Wade (1989) further describe some of the sleep incompatible behaviours which are engaged in by some patients: firstly, they may organise many of their daily activities around the bed and bedroom, which in terms of Bootzin's operant theory of insomnia, would be expected to reduce the power of the sleeping environment as a cue for sleep; secondly, they often maintain highly irregular sleep/wake schedules, which sleep hygiene research suggests is very disruptive to sleep; and lastly, they may spend a large proportion of the day lying down, which Spielman *et al.* (1987) theorise would fragment rather than consolidate sleep.

It seems, therefore, that although sleep disturbance in chronic pain may be precipitated by the underlying medical condition, a number of other factors may play an important role. It is noted, however, that none of the theoretical explanations given above include consideration of cognitive factors.

## 1.7 Outcome Studies

Only a minority of studies have investigated specifically the responses of patients with chronic pain to non-pharmacological interventions for insomnia. These are summarised below:

Using A:B single case designs, Varni (1980) found a treatment package consisting of a variety of relaxation procedures and stimulus control instructions significantly increased the duration of sleep in a 38 year old haemophiliac with a history of chronic insomnia, and Morin, Kowatch & Shanick (1990) used sleep restriction therapy to effectively increase the sleep duration of a depressed in-patient on a psychiatric unit who had concomitant chronic pain. In a study of three patients with chronic pain conditions who had severe and persistent insomnia, Morin *et al.* (1989) used a multiple-baseline single case design to demonstrate substantial improvements in sleep pattern following a multi-component treatment comprising both stimulus control and sleep restriction therapy procedures.

In a group controlled study of cancer patients, Cannici, Malcolm & Peak (1983) found relaxation training effective in reducing sleep latency, but it must be noted that only half the participants in this study reported being in pain. Treves (1993) found the administration of a self-help package (comprising stimulus control instructions and a relaxation tape) to a group of 15 out-patients attending a pain clinic resulted in both statistically and clinically significant improvements in sleep duration and sleep quality, although sleep diary return rates were poor (47 per cent).

Although not specifically targeted at alleviating insomnia, PMPs comprise a number of interventions which would be expected to benefit sleep (e.g. relaxation, graded exercise and

cognitive therapy). The measurement of insomnia in pain management studies is very rare, however, even though patients attending PMPs almost universally report problems with their sleep (Williams, 1995). Linton, Melin & Stjernlof (1985) found the sleep of a sample of eight patients receiving standard clinic treatment plus relaxation and operant activity training showed superior improvements to a sample who received the standard clinical treatment alone, and Staedt, Windt, Hajak, Stoppe, Rudolph, Ensink, Hildebrandt & Ruther (1993) found improvements in disturbances of sleep in patients attending an eight week physical rehabilitation programme, but no improvements in sleep efficiency. In neither study was the treatment a 'true' PMP, as defined by current terms (Working Party of the Pain Society, 1995), however, and both relied on restricted and atypical measures of sleep.

### **1.8 Rationale for the Current Study**

To summarise, therefore, insomnia is a significant problem for many patients who have chronic pain. Although in primary insomnia, much work has been carried out in investigating the nature of the problem, and developing effective psychological interventions, very few studies have been similarly conducted in chronic pain. In addition to recognising the role played by pain itself, theoretical proposals suggest the importance of behavioural and emotional factors in maintaining the problem, and the few outcome studies using interventions based on these principles have yielded promising results. Studies have, however, tended to be conducted on patients where the type of chronic pain condition has been atypical, and the response to treatment of patients attending PMPs has not been investigated. In spite of the evidence that cognitive variables are an important factor in mediating responses to both insomnia and chronic pain, neither theoretical explanations or approaches to treatment for insomnia associated with chronic pain have included consideration of these factors. In addition, exploration of the



experiences of people with insomnia and chronic pain, and its treatment, has been neglected.

The first aim of the current study therefore is to investigate the effect of attending a PMP, and receiving an additional intervention for insomnia, on the sleep pattern and quality of individual patients who have chronic pain and complain of problems in sleeping. The study design takes into account the recommendations made by recent reviewers regarding the use of multi-component therapies which are tailored to the needs of the individual, and to include consideration of the clinical significance of change when evaluating outcome. Cognitive therapy approaches are included in the multi-component intervention and measures of distress and self-efficacy are subsequently included in the assessment of treatment efficacy.

A single case design is chosen to evaluate outcome. Compared with nomothetic approaches, this type of design allows the particular pattern of improvement in the individual patient to be examined and for the clinician, it has the advantage of enabling treatment plans to be individualised (Long & Hollin, 1995). Single case designs have been used extensively to evaluate outcome in insomnia research (e.g. Espie & Lindsay, 1985; Edinger, Hoelscher, Marsh, Lipper & Ionescu-Piogga, 1992). They are readily integrated into clinical practice (Peck, 1985) and where the clinician has access to a relatively homogeneous population, a replication series can be conducted which allows for the generalisation of results across the specific individual being studied (Barlow & Hersen, 1984; Morley, 1996).

The second aim of the current study is to explore the experiences of people with insomnia and chronic pain and its treatment using qualitative methods. The interpretative phenomenological approach (IPA), as an approach rooted in grounded theory, is particularly concerned with



understanding what a particular respondent thinks or believes about the topic under discussion. It has been specifically recommended for use within health psychology as a means of exploring how individuals cope with the stresses of chronic illness (Smith, 1996b), and is therefore chosen as a methodology appropriate for use in the current study.

Although, the single case and IPA approaches stem from different philosophical backgrounds, the two methodologies are used in the current study to *compliment* each other (Barker, Pistrang & Elliott, 1994, pp.83). A strong connecting thread between the two strands of enquiry is the focus on cognitions. In evaluating the efficacy of a treatment which includes a cognitive therapy component, a phenomenological approach facilitates a close and detailed analysis of participant beliefs both pre and post-treatment. In addition, examination of participant experiences of insomnia and chronic pain, and its treatment, may yield important factors for future empirical investigation, in an area which has as yet received little attention.

## **RESEARCH AIMS**

(1) To investigate the effect of attending a PMP, and receiving an additional individual cognitive-behavioural intervention for insomnia, on (a) the sleep pattern and quality, and (b) the level of distress and ability to cope with poor sleep, of individual patients who have chronic pain and complain of problems in sleeping.

(2) To explore the psychological processes which determine and maintain the relationship between participants' experience of chronic pain and insomnia, and their response to treatment.

## **RESEARCH QUESTIONS**

(1) What is the effect of attending a PMP, and receiving an additional individual cognitive-behavioural intervention for insomnia, on (a) the sleep pattern and quality, and (b) the level of distress and ability to cope with poor sleep, of individual patients who have chronic pain and complain of problems in sleeping?

(2) What are the psychological processes which determine and maintain the relationship between participants' experience of chronic pain and insomnia, and their response to treatment, and do they correspond with those identified in previous research?

## **METHOD**

### **3.1 Setting**

The study took place within the context of a residential PMP. The programme is cognitive behavioural in orientation and run by an interdisciplinary team of anaesthetists, clinical psychologists, physiotherapists, occupational therapists and nurses, all of whom are experienced in their respective fields and trained in the cognitive behavioural management of pain. Groups of between ten and twelve patients are admitted to the PMP simultaneously. They reside in hostel accommodation for the programme duration but return to their own homes at weekends. Programme components include stretch and exercise, goal setting, pacing, relaxation, medication reduction and cognitive therapy (Appendix 1). A description of the programme can be found in Williams (1993a) and details concerning outcome in Williams (1993b), Williams (1996) and Williams *et al.* (1996).

### **3.2 Design**

In order to investigate both research questions (1) and (2), and to facilitate ease of reading, the study is divided into two parts:

**Part I.** This part of the study employed a multiple single case experimental design with one month follow-up using repeated measures.

There were five phases of the study: A, B, A', B' and A''. Phases A, A' and A'' represented periods where participants were in their normal sleep environment (i.e. home). During phases

B and B' participants were resident on the PMP. These were also the phases where the interventions were introduced. It was not anticipated that treatment effects would be withdrawn once participants returned to their homes because they were being actively encouraged to implement the pain and sleep management strategies they had learned. The effectiveness of the treatment was therefore judged by the extent to which the data points shifted in the direction of improvement *once the interventions had been introduced and the patient had returned to his/her normal sleep environment (i.e. phases A' and A'')*.

In their classic text on single case methodology, Hersen and Barlow (1976) state that "the most obvious limitation of studying a single case is that one does not know if the results from this case would be relevant to other cases" (pp.52). In an attempt to establish the reliability of findings and their generality across clients, the experimental design was therefore replicated across participants according to guidelines for direct replication set by Hersen & Barlow, 1976, pp.334-335.

### **Guidelines for direct replication.**

- (1) Therapists and settings should remain constant across replications.
- (2) The behaviour disorder in question should be topographically similar across clients.
- (3) The client background variables should be as closely matched as possible (although the ideal goal of identical clients can never be attained in applied research).
- (4) The procedure employed should be uniform across clients, until failures ensue.

**Part II.** A one group descriptive design was used in this part of the study. In order to gain a range of subjective experiences and accounts, no restrictions were placed on participants' sex,



age, pain site, chronicity and programme type.

### **3.3 Participants**

**Part I: Selection.** Participants in this part of the study were selected from two intakes of patients (n=21) who had been found suitable to attend the PMP according to set criteria (Appendix 2), and were being admitted to a four week programme split into two fortnights. This programme format was the most suitable for the ABA'B'A'' format of the study and allowed for an extended period of self-monitoring.

**Inclusion criteria.** In order to take part in the study participants needed (a) to have their standard pre-treatment appointment scheduled for at least 10 days prior to admission (for baseline monitoring); (b) to report a significant problem in sleeping as a result of their chronic pain; and (c) to agree to take part.

**Part I: Characteristics.** Of the 21 patients attending the split PMPs, 11 had pre-treatment appointments scheduled in sufficient time for them to participate. Of these, two declined to take part because they did not feel their sleep was significantly disturbed, and one declined because she preferred not to take part. *This left a final sample of eight participants in this part of the study.*

The median age of these participants was 47 years (range 33-64 years); five were female and three were male. The median duration of their pain was 13 years (range 3-40 years). All participants' pain was musculoskeletal in origin; seven described their main site of pain as in their back and one as in their neck. Two participants were taking benzodiazepines, three were

taking analgesics and three were taking tricyclic antidepressants to help them sleep at night.

**Part II: Selection.** Participants in Part II of the study comprised the eight patients from Part I of the study and in order to increase the sample size, and variability of problems, an additional seven patients attending a two week programme were also recruited. In order to take part the latter group of participants needed to meet inclusion criteria (b) and (c) only (see pp. 22).

**Part II: Characteristics.** Of the 12 patients attending the two week programme, seven met the inclusion criteria. *A total of 15 participants, therefore, took part in Part II of the study.* The median age of these participants was 43 years (range 28-64 years); nine were female and seven were male. The median duration of their pain was 10 years (range 1-64 years). Ten described their main pain site as their lower back, two as their upper back or neck, one as their shoulder/arm/hands, one as their head and one as their hips/legs/feet. Three participants were taking benzodiazepines, four were taking analgesics and three tricyclic antidepressants to help them sleep at night.

### **3.4 Consent**

The study adhered to the ethical guidelines of both the British Psychological Society (BPS, 1993) and International Association for the Study of Pain (IASP, 1995). Approval was obtained from the relevant hospital research ethics committee (Appendix 3). A letter and study information sheet was sent to all participants (Appendix 4 & 5) and they each spoke individually with the principal investigator concerning the nature of the study. If they wished to take part, their written consent was obtained (Appendix 6).

### **3.5 Measures: Part I**

In accordance with the recommendations of Morley (1996), both *target* and *global* measures of change were collected. Target measures are the main outcome measure in single case research. In order to examine possible trends and fluctuations over time, they are administered frequently and repeatedly, usually over extended time periods. Global measures are standard measures, developed for known populations and problems, which can provide information on the generalisability of target measures.

Participants completed target measures on a daily basis and global measures at their pre-treatment appointment, post-treatment (seven weeks later) and at one month follow-up.

#### **Sleep Measures.**

**DSD: Daily Sleep Diary (Haythornthwaite, Hegel & Kerns, 1991).** The study used a sleep diary specifically designed for chronic pain patients (Haythornthwaite, Hegel & Kerns, 1991), which has also been utilised in other studies assessing sleep disturbance in this population (Wilson *et al.* 1998). In a study of its use with 46 patients attending an in-patient PMP, Haythornthwaite *et al.* (1991) reported the DSD to have acceptable (although relatively low) reliability and validity scores: the coefficients of stability for individual items were all significant at  $p < .05$ , and ranged from .36 to .62; repeated measures analyses of variance found each DSD measure to be stable over a period of four days; and patients' diary scores were found to be significantly correlated with both retrospective measures of sleep and constructs known to be conceptually and clinically related to sleep among chronic pain patients (i.e. severity of pain, anxiety and depression), with correlations of between .29 and .50 ( $p < .05$ ;  $p < .01$ ).



The sleep diary was completed by participants from the day of their pre-treatment appointment, during their stay on the PMP and the mid two weeks where they returned home, to the day of their one month follow-up appointment (76-78 days in total). They were required to record the time of sleep onset, the time of awakening, an estimate of the number of hours slept (sleep duration), the length of sleep onset (sleep latency), the number of wakes which resulted in trouble falling back to sleep (awakenings) and the quality of their night's sleep (quality). These latter four items constituted the main target measures in the current study. (Appendix 7)

**PSQI: Pittsburgh Sleep Quality Index (Buysse, Reynolds, Monk, Berman & Kupfer, 1989).** The PSQI was chosen in preference to other sleep questionnaires because it has now been used in a small number of studies with chronic pain patients (e.g. Wilson *et al.* 1998), and in contrast to some other measures, its reliability and validity have been examined. It is a self-rating measure which retrospectively assesses sleep quality and disturbance over a one month time interval. The 19 individual items in the scale were derived following a review of previously used questionnaires and clinical experience; they yield seven 'component' scores, which when summated comprise an overall total score.

Analysis of scores from a large (n=148) clinical and 'normal' population (Buysse *et al.*, 1989) indicated good reliability and acceptable validity data. Validity was mainly assessed by determining the degree to which the PSQI detected differences between groups recognised as clinically distinct ('normals', depressed, sleep onset insomnia and sleep maintenance insomnia). Distinctive score profiles and significant differences in global scores ( $p<.001$ ) were found between these four clinical groups. The test-re-test correlation coefficient for total PSQI scores

was found to be 0.85 ( $p < .001$ ). Using a cut-off score of five for total PSQI, the instrument was able to distinguish good from poor sleepers (i.e. the 'normal' sample v.s. the clinical sample) with a diagnostic accuracy of 89.6 per cent and specificity of 86.5 per cent ( $\kappa = 0.75$ ,  $p < .001$ ). (Appendix 8).

**DNRS; SENRS: Sleep Distress and Self-Efficacy Scales.** These two six point numerical rating scales were designed by the author specifically for use in this study and were similar in style to the pain numerical rating scales patients completed on the programme. Participants were asked to rate (a) how much *distress* their difficulty in sleeping had caused them over the past month; and (b) how *confident* they would say they had been in their ability to *cope* with their difficulty in sleeping; on a numerical scale from nought to five, with the nought representing one extreme (i.e. *low* levels of distress/confidence) and the five representing the other extreme (i.e. *high* levels of distress/confidence). (Appendix 9) The reliability and validity of the DNRS and SENRS was not examined.

**Sleep related medication.** This included analgesics, tricyclic antidepressants and benzodiazepines where the patient reported the medication was being taken at night for help with sleep. Medication dose and frequency of use was recorded.

### **PMP Outcome Measures.**

The following global measures were selected as measures of cognitive and emotional functioning which have all been used extensively in studies of chronic pain patients, and were routinely collected as part of the assessment battery at the PMP:



**HADS: Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983).** This is a brief measure of anxiety and depression standardised on medically ill populations which does not contain somatic items. The anxiety subscale is mostly made up of items from the Present Status Examination and the depression subscale items are largely based on an anhedonia model of depression. Using a cut-off score of 11 or less, the two subscales were found by Zigmond & Snaith (1983) to identify 'caseness' (as defined by joint interview by two psychiatrists) in 99 and 95 per cent of patients respectively, and to correlate significantly (0.70;  $p < .001$ ; 0.74;  $p < .001$ ) with psychiatric ratings of mood severity. However, Zigmond & Snaith (1983) recommend an even stricter cut-off score of nine or less when the scale is being used in research where a low proportion of false negative classification is required.

The convergent validity of the two subscales was examined by Aylard, Gooding, McKenna & Snaith (1987). The anxiety subscale was found to correlate significantly (0.67;  $p < .01$ ) with the Clinical Anxiety Scale (Snaith, Baugh, Clayden, Husain & Sipple, 1982), and the depression subscale to correlate significantly (0.77;  $p < .01$ ) with the Montgomery-Asberg Depression Rating Scale (Montgomery & Asberg, 1979). To the author's knowledge, no studies of test-re-test reliability have been carried out on the HADS: clearly this would have been desirable for a questionnaire being used in a repeated measures design. The depression subscale also suffers from the exclusion of items assessing the cognitive aspects of depression.

**PSEQ: Pain Self-Efficacy Questionnaire (Nicholas, 1989).** This is a 10 item scale, which patients answer in terms of confidence in being able to do a range of activities or to cope in spite of pain. Low self-efficacy has been found to have a strong correlation with high disability and distress associated with pain (Jensen, *et al.*, 1991) and has been shown to be a predictor



of drop-out from pain management (Coughlan, Ridout, Williams & Richardson, 1995). Internal consistency has been found to be 0.92 and test-re-test reliability over a period of 11 weeks 0.79 (Nicholas, 1989). (Appendix 10)

**CSQ: Coping Strategies Questionnaire (Rosentiel & Keefe, 1983).** This is used to score frequency of use of a range of cognitive and behavioural strategies used to try to cope with pain. The cognitive style most reliably found to be negatively associated with treatment outcome is catastrophising (the tendency to expect the worst outcome of a situation) and in a recent large sample analysis by Robinson, Riley, Myers, Sadler, Kvaal, Geisser, & Keefe (1997) it emerged as a single factor with an alpha of 0.84. This sub-scale alone is thus reported. Although test-re-test reliability has not been assessed, the measure is selected because it is widely used in PMP outcome studies and the tendency to catastrophise has been found to be predictive of patients' adjustment to chronic pain (Jensen *et al.*, 1991). (Appendix 11)

### **3.6 Measures: Part II**

**Semi-Structured Interview.** In IPA, Smith (1995) advocates the use of semi-structured interviews because they allow the interviewer to gain a rich and detailed picture of a respondents' beliefs. They also enable the interviewer to follow up the respondent's particular concerns, and probe areas as they arise. Using the findings of previous research on primary insomnia and insomnia associated with chronic pain, a set of questions were selected to explore participants' experience and beliefs concerning disturbance of their sleep (Appendix 12). The questions were phrased and ordered according to Smith's (1995) guidelines for the construction of a semi-structured interview schedule, and successfully piloted by the

investigator in the course of her normal clinical practice on five patients attending the Unit for their initial screening interview.

The final schedule was not intended to be prescriptive, but to act as a guide for an interview which facilitated the participant giving their own view. Prompts were therefore given and questions rephrased, or asked in a different order, as appropriate. In addition to providing the material for Part II of the study, the semi-structured interview allowed the investigator to begin to formulate sources of particular distress or difficulty with sleep for those participants also taking part in Part I of the study.

### **3.7 Intervention (Part I participants only)**

Participants' first two weeks of treatment on the PMP continued as per normal practice (see Setting). On the second day of the second week they attended a routine general group session on sleep, which lasted for one hour and was run by nursing staff. See Appendix 13 for the standard handout given to PMP attenders which summarises the content of this session.

As part of the study, participants then attended an individual 30 minute session with the investigator during the second two weeks on the PMP. In view of the recommendations for future directions in insomnia research, this session was multi-component in nature and whilst using the same cognitive-behavioural principles, was tailored to the needs of each individual client. Given the context of the PMP, its main aim was to help participants to generalise and apply the strategies they were learning concerning the management of their pain, to their difficulty with sleeping. Information gained from the sleep diaries and semi-structured interview from Part II of the study was used to identify the main areas of concern and to

thereby guide the session. A problem solving framework was used and positive reinforcement was given where helpful strategies were already being applied by participants.

The following elements of the programme were included in the session: exercise to promote good sleep; stretch to alleviate stiffness at night and on waking in the morning; pacing during the day to prevent the exacerbation of pain at night-time; relaxation to facilitate sleep onset, manage periods of wakefulness and help control 'racing thoughts'; reduction of sleep related medication; and modifying unhelpful cognitions in order to prevent and manage cognitive and emotional arousal at night (e.g. 'Even if I'm not asleep, I am resting, which is restorative.'). Where appropriate, both sleep hygiene and stimulus control advice covered in the initial group session were re-iterated, particularly advice concerning sleep scheduling.

Studies have found that on average, insomnia patients forget approximately one third of the recommendations given to them by clinicians (Chambers, 1992). In order to facilitate recall, the main points discussed in the individual session were therefore summarised in a letter to each participant. The letter was given to them at the end of their third week (See Appendix 14 for an example letter). Participants were informed that they would be unlikely to experience immediate improvement in their sleep and that they would need to persist with changing their habits for several weeks before any benefit would be gained. These counter demand instructions were used to control for non-specific factors in therapy such as expectancy effects and demand characteristics (Steinmark & Borkovec, 1974).



### **3.8 Procedure**

#### **Part I.**

**Phase A: Baseline.** Participants were residing at home from the day of their routine pre-treatment appointment to admission (usually 10-12 days).

**Phase B: PMP.** Participants' treatment on the PMP continued as per normal practice (see Setting). They were admitted to hostel accommodation on the hospital site for an initial two weeks, staying from Sunday night to Wednesday night and returning to their homes on Thursday evening (for the weekend).

**Phase A': Post-PMP.** Participants returned to their homes for a two week period (sixteen days including weekends).

**Phase B': PMP plus individual session.** Participants were re-admitted to hostel accommodation on the hospital site for a two weeks, staying from Sunday night to Wednesday night and returning to their homes on Thursday evening (for the weekend). Their treatment on the PMP continued as per normal practice apart from their attending the individual session with the investigator on their return to the PMP.

**Phase A'': Post PMP plus individual session.** Participants returned to their homes for a period of four weeks.

#### **Part II.**

The semi-structured interview took place in the investigator's office at the PMP at

participants' pre-treatment appointment. It lasted between 15-30 minutes and a tape recorder was used throughout to record respondents' responses. Participants were informed that they would be asked to talk about their sleep, and the way it was affected by their experience of pain, in response to questions and prompts given by the interviewer. Information given at the time of consent concerning the use of the tape recorder was reiterated (i.e. that the recording and tape cassette would not contain any identifier, and that the tape would be wiped clean at the completion of the study).

Conditions were the same for the post-treatment interview but due to time constraints, this interview was not tape recorded. Careful notes were made of participants' responses to questions.

### **3.9 Data Analysis: Part I**

**Graphical Analysis.** In order to investigate shifts in the four sleep diary measures over the course of attendance at the PMP, changes in three different aspects of the data were considered:

**Central Tendency.** The broadened median (BMED) (Rosenberger & Gasko, 1983) was chosen as the measure of central tendency because it is resistant to the influence of outliers, highly sensitive to a reasonable proportion of the data and suitable for small samples. In accordance with the recommendations of Morley & Adams (1991), it was drawn as reference line superimposed on the raw data time series.

**Trend.** A trend is a systematic shift in the value of the central location of the data set over

time. In view of the variability in much of the raw data from the current study, running medians were chosen in preference to linear methods of investigating trend. In order to obtain smoothed curves, running medians of four averaged by pairs (RM42) were calculated and shown superimposed on the raw data time series.

**Variability.** In some instances, data in the current study were highly variable. In order to investigate changes in the degree of variability over the course of the study, the trended range was chosen (see Morley & Adams, 1991 for calculation). This displays variability independently of any change in central tendency and is shown as two lines superimposed on the raw data series. The method can be applied using a trimmed range, where it is suggested that the extreme values within each half are trimmed by 10-20 per cent. This was used in the current study in order to remove the influence of outliers.

**Statistical Analysis.** The use of statistical analysis in single case methodology has been subject to debate (Peck, 1985; Long & Hollin, 1995). Morley & Adams (1989), however, recommend its use as a means of ensuring that baseline data are stable, as well as checking inferences made by visual inspection of graphs.

In order to investigate intervention effects, without the possible interference of a change in sleeping environment, statistical analysis examined trends in mean between conditions (a) A (baseline) and A' (post-PMP); and (b) A (baseline), A' (post-PMP) and A'' (post-PMP plus individual session). Kendall's Tau (corrected for ties) was chosen as a powerful test of trend in mean suitable for the analysis of single case data (Morley & Adams, 1989). In accordance with convention, alpha was set at  $p < .05$  and because research into the effects of intervention



in this population is still in its infancy, and the direction of change could not therefore be confidently predicted, two tailed tests were used.

**Clinical Significance.** In accordance with the recommendations for future directions in insomnia research, the clinical significance of changes in both sleep and PMP outcome measures was examined.

Several methods have been designed to examine the clinical significance of treatment effects for various disorders. Jacobson & Truax's (1991) proposals for the evaluation of clinically significant change include the criteria that the individual's post-intervention score moves outside of the range of the dysfunctional population (usually defined as two standard deviations away from the mean of the dysfunctional population), and from the dysfunctional to nondysfunctional (i.e. healthy) group. In research concerning the efficacy of psychological treatments for primary insomnia, criteria have included the proportion of patients achieving an improvement of at least 50 per cent in measures of sleep disturbance (Espie, *et al.*, 1989), in addition to cutoff scores for normative functioning (e.g. sleep latency of 30 minutes or less) (Lacks & Powlishta, 1989).

Scrutiny of the measures, however, reveals difficulties were these criteria to be applied in the present study: firstly, with the exception of the HADS and PSQI, normative data on a nondysfunctional sample are not available for the measures being used; secondly, in some instances, defining the criteria for clinical significance as a change of two standard deviations above or below the mean of the dysfunctional population, yields extremely strict criteria (e.g. a score of 0 on the catastrophising subscale of the CSQ); and finally, with regards to the sleep

measures in particular, it is important to recognise that the population being studied have an intractable pain condition, and it would therefore seem inadvisable to apply exactly the same criteria as have been used in outcome studies on people with primary insomnia, or that place their post-treatment scores within the range of a pain-free ('normal') population.

The criteria for clinically significant change on the sleep diary measures was therefore set at what were deemed to be clinically meaningful levels. For DSD sleep duration this represented an improvement in BMED sleep duration of at least 30 minutes, and for DSD sleep latency, awakenings and quality this represented an improvement in BMED score of 25 per cent or more. For the PSQI: a post-treatment or follow-up score 25 per cent lower than that obtained at pre-treatment was applied and for DNRS and SENRS, an improvement in post-treatment or follow-up score of two scale points compared with pre-treatment. The criteria set for sleep related medication were (a) making *any* reduction in sleep-related medication; and (b) not taking any medication related to sleep, at follow-up.

With regards to the PMP outcome measures, the criteria for clinically significant change were set according to normative data on the anxiety and depression subscales of the IIADS (a move to a score of less than or equal to nine). For the PSEQ and CSQ, the actual questionnaires and statements were examined. Both comprise a series of statements where participants use seven point rating scales: on the PSEQ for rating confidence in performing a certain activity (e.g. for 'I can cope with my pain in most situations', nought represents 'not at all confident' and six represents 'completely confident'); and on the CSQ for rating frequency of use of each coping strategy (e.g. for 'It [the pain] is awful and I feel that it overwhelms me' nought represents 'never do' and six represents 'always do that'). Achievement of a mean of four per item on the

item on the PSEQ and one per item on the CSQ were thought to approximate levels which were not of clinical concern. Using this standard, the criteria for clinically significant improvement on the PSEQ and CSQ were movement to scores greater than or equal to 40 on the PSEQ and less than or equal to six on the CSQ.

## **2.10 Data Analysis: Part II**

The verbatim transcripts of the 15 interviews and notes from follow-up interviews served as the raw data to be analysed. An interpretative phenomenological method of analysis, as described by Smith (1995) was used to identify the main themes arising from the data (see below):

- (1) The first eight interview transcripts/notes were read, and re-read a number of times, to ensure a general sense was obtained of the participants' accounts. During this stage notes were made in one margin of potential themes. The process was informed by the researcher's experience of the interview itself.
- (2) Returning to the beginning, the text was re-read and any emergent themes were written in capitals in the other margin.
- (3) The remaining eight interview transcripts/notes were then read and subjected to the same process. It was checked that no new themes emerged and that themes identified in the second set of transcripts/notes were consistent with those identified in the first.
- (4) Attention was then focused on the themes themselves to define them in more detail and



establish their inter-relationships. The focus was on the psychological content of the phenomenon under study and the data now being condensed.

(5) The shared themes were organized to make consistent and meaningful statements which contributed to an account of the meaning and essence of the participants' experience grounded in their own words.

See Appendix 14 for example.

**Reliability and Validity.** The issue of evaluating the reliability and validity of qualitative research is still an issue of debate among psychologists. One view expressed by several researchers is that since qualitative enquiry has different epistemological roots to quantitative psychology, it is important that it should be judged against criteria that are appropriate to the approach (Smith, Harre & Van Langenhove, 1995). Issues concerning the generalisability of results (e.g. sample size, statistical power and participant selection) are therefore considered to be of less importance than the applicability of the concepts and themes arising from the analysis (Conrad, 1990).

To assess the internal validity and reliability of qualitative research, two important criteria are proposed by Smith (1996a): internal coherence, defined as "the need to concentrate on whether the argument presented in the study is internally consistent and justified by the data" (Osbourne & Smith, 1998, pp.68); and presentation of evidence, which refers to the need to present in the paper "sufficient verbatim evidence from the participants ... to allow the reader to interrogate the interpretation" (Osbourne & Smith, 1998, pp.68).

As a check on the internal coherence of the analysis, the transcripts/notes were independently examined by a clinical psychologist with five years' experience of working in the field of chronic pain who was employed at another PMP. The meaning of participants' statements was discussed and agreement reached on appropriate theme categories. This procedure aimed to ensure that the investigator's analysis of the transcripts was supported by the data and had been systematically achieved, rather than aiming to achieve satisfactory inter-rater reliability. With regards to the need to present evidence so that the reader can interrogate the interpretation, specific quotations or clips were selected from the raw transcripts to present as illustrations of the themes.

### **3.11 Research Diary**

IPA recognises that whilst one of its aims is to explore the participants' view of the phenomenon under study, the researcher's conceptions will inevitably influence this process (Smith, 1996b). A research diary was therefore kept over the duration of the study. It recorded research decisions and the investigator's thoughts, feelings and experiences as the study developed (see Appendix 15 for excerpts).

## **RESULTS**

### **PART I**

**The effect of attending a PMP, and receiving an additional individual cognitive-behavioural intervention for insomnia, on (a) the sleep pattern and quality, and (b) the level of distress and ability to cope with poor sleep, of individual patients who have chronic pain and complain of problems in sleeping.**

#### **4.1 Attrition**

Of the eight participants (P) in Part I of the study, complete sleep diary data were available for five participants (completers). Two participants (P3 & P7) reported their baseline diaries as lost, and one participant (P5) was unable to complete the follow-up diaries because she was admitted to hospital. These three participants (non-completers) were therefore excluded from the sleep diary analysis but details of the intervention they received, their performance on global measures of change, and post-treatment comments are still presented. Pre-treatment sleep distress (DNRS) and self-efficacy (SENRS) scores were only available for five participants due to an administrative error. Complete post-treatment and follow-up data are available for seven and six participants, respectively.

#### **4.2 Outcome**

Pre-treatment scores for the sleep and PMP outcome measures are presented in Appendices 17 and 18. Table 1 summarises the sleep problems and individualised intervention received by all Part I participants. Salient points regarding the formulation of their problems are also given.



**Table 1. Summary of sleep problems and tailored intervention for all Part I participants.**

Background Information	Problem summary	Formulation (summary of salient points)	Tailored intervention
P1. 54 year old man Low back pain radiating to legs following assault 5 years ago	Sleep onset & maintenance insomnia Wakes feeling unrefreshed Helplessness re. sleep PSQI=16	Reports pain makes it 'impossible' to get comfortable Delays going to bed until late to maximise chances of falling asleep Believes the average person falls asleep within seven minutes Helplessness. Tried 'many, many' ways to help him sleep. to no avail Believes lack of sleep is causing further damage to health. Remains in bed in morning	Establish wind-down period using stretch and relaxation Improve sleep and activity scheduling Challenge beliefs re. average sleep onset. amount needed & helplessness
P2. 49 year old woman Low back pain radiating to left leg following birth of child 22 years ago	Describes insufficient sleep (<5hours) Early morning wakening PSQI=13	Remains in bed for two hours after waking; states 'the day has to drag on' Inactive and rests frequently during the day due to fatigue Unable to get comfortable - only able to lie on her stomach Woken by frequent dreams (not distressing) - 'That's not usual is it?' Relies on amitriptyline to initiate sleep	Encourage increased exercise and activity with minimal rest periods Graded practice: lying in other positions Information re. nocturnal dream patterns Encourage reduction of amitriptyline
P3. 33 year old man Low back, hip and neck pain. Onset 13 years ago - no specific aetiology	Sleep onset and maintenance insomnia Highly variable sleep pattern Intermittent use of amitriptyline to initiate sleep but dislikes effects PSQI=13	Delays going to bed until late to maximise chances of falling asleep When unable to sleep at night, gets up and uses computer - likes to be stimulated Cognitive arousal and discomfort prevent sleep: 'My head says 'shut down time', go to sleep, and my body says you're having a laugh!' Daytime overactivity leads to increased pain at night triggering poor sleep over several days, and subsequent use of amitriptyline	Encourage regular bedtime Discourage stimulating activity at night Use of relaxation and stretch Pacing throughout the day to prevent overactivity Increased exercise
P4. 45 year old man Low back pain radiating down hip and leg following lifting injury at work 13 years ago	Sleep onset insomnia Occasionally woken by leg cramps Highly variable sleep pattern PSQI=12	Delays going to bed until late to maximise chances of falling asleep. Uses computer until then - leads to arousal and increased pain through prolonged sitting. Going to bed earlier leads to cognitive and emotional arousal - 'If I go to bed at twelve o'clock, I lay there for two or three hours, getting more irritated.'	Stretch & relaxation at bedtime Graded approach to an earlier bedtime Discourage use of computer Challenge thoughts about not sleeping
P5. 37 year old woman Low back and leg pain following injury at work 3 years ago	Sleep onset and maintenance insomnia Complains of poor quality sleep PSQI=15	When unable to sleep at night, watches TV - often falls asleep on recliner not bed Overdoing during the day leads to increased pain at night, which prevents sleep Low self efficacy and external locus of control - 'the only time I get any sleep is when they give me painkillers [in hospital]'	Use of relaxation to help reinitiate sleep Reduce use of recliner - need to retrain body to recognise bed as a cue for sleep Encourage self-management
P6. 43 year old woman Low back pain radiating to lower and upper limbs following pregnancy 20 years ago	Uses amitriptyline for sleep onset Difficulties with sleep maintenance Poor sleep disturbs partner PSQI=17	Unable to get comfortable which leads to cognitive and emotional arousal Sleep disturbed by frequency of micturition following hysterectomy. Visiting toilet downstairs leads to further waking. Husband accompanies her due to drowsiness from amitriptyline	Challenge thoughts about not sleeping Refer to physiotherapist for advice re. frequency of micturition Encourage reduction in amitriptyline
P7. 49 year old woman Neck, head, shoulder and arm pain severe for 3 years following whiplash 20 years ago	Sleep onset and maintenance insomnia Wears a neck collar at night PSQI=16	Cognitive & emotional arousal when unable to sleep: 'when the pain disturbs you, you do get angry. I'd be lying if I said different' When woken by pain in her neck feels anxious, fearing 'it [my neck] goes loose... and [it] will throw my spine out'	Encourage cessation in use of collar Encourage helpful cognitions about sleep & PMP techniques already being implemented
P8. 63 year old woman Low back, buttock and knee pain following pregnancy 40 years ago	Sleep maintenance insomnia Tired and stiff on waking Concerned is getting too much sleep PSQI=8	Woken by pain. Cognitive arousal further prevents sleep: '[It's difficult] to switch off ... all sorts of things are going through my brain ... I feel like I'm wasting time'. Does administration and uses computer at night Naps of <2 ½ hrs in the day - describes as 'bizarre' and 'not normal'	Encourage strategies already implemented i.e. use of relaxation & cessation of daytime napping Information about amount of sleep

Note. Score <5 on the PSQI falls within the range of good sleepers; score 5 < falls within range for insomnia.

**Sleep Diary.** See figures 1-5.

No significant trend in mean was found for any of the baseline sleep diary data.

Graphs of sleep latency or sleep maintenance are only presented where completers reported a significant difficulty with this area of sleep (see Table 1). Participant report, rather than baseline sleep diary data, was used to define the presence of difficulties because it indicated participant distress related to this area of their sleep, and in some instances, mean baseline DSD sleep latency scores were low because participants were using medication (P2 and P6), or coping strategies such as delaying bedtime (P4) to help them sleep.

Although analysis of the efficacy of treatment focusses on phases A, A' and A'', data from phases B and B' are also plotted to examine any changes during residency at the PMP.



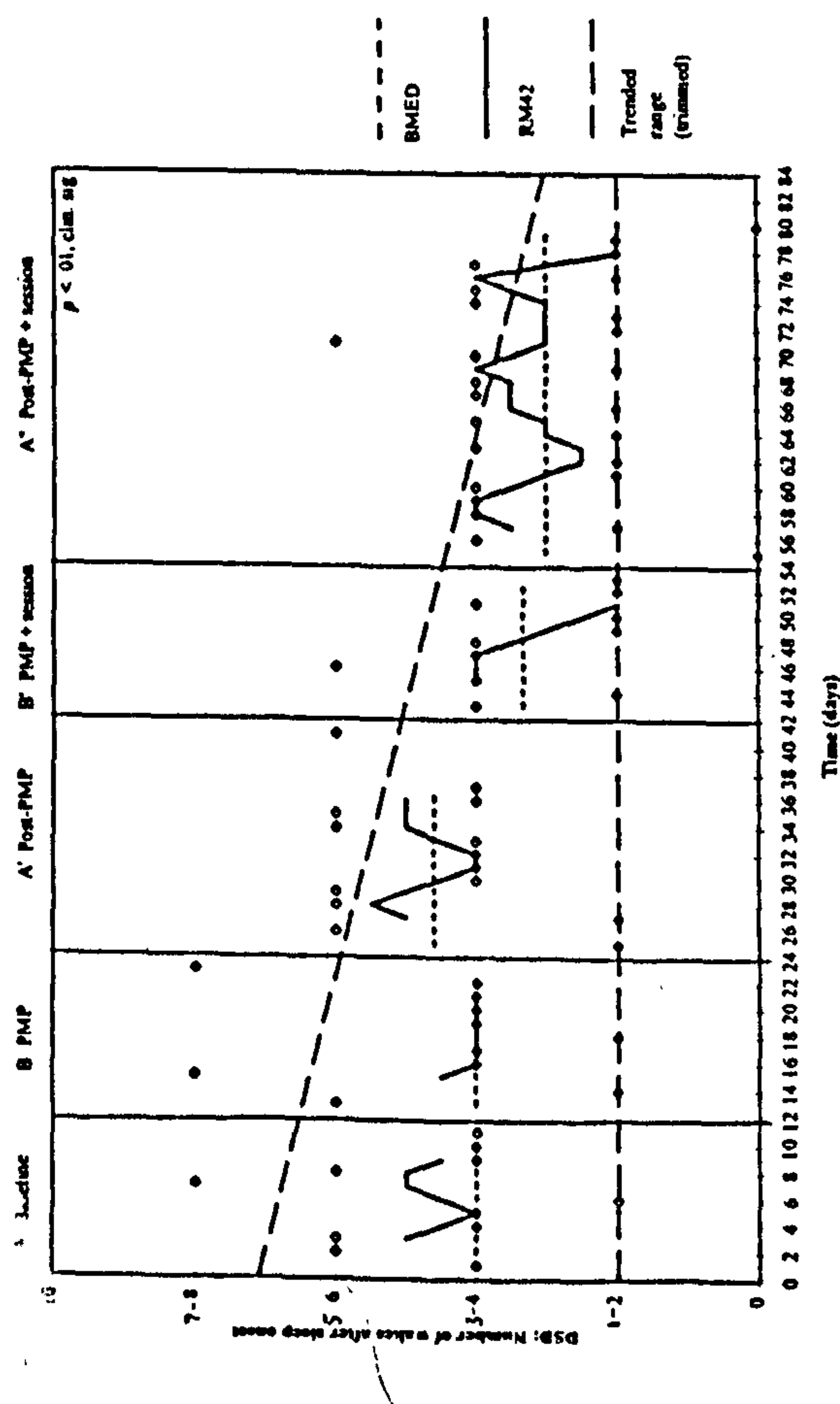
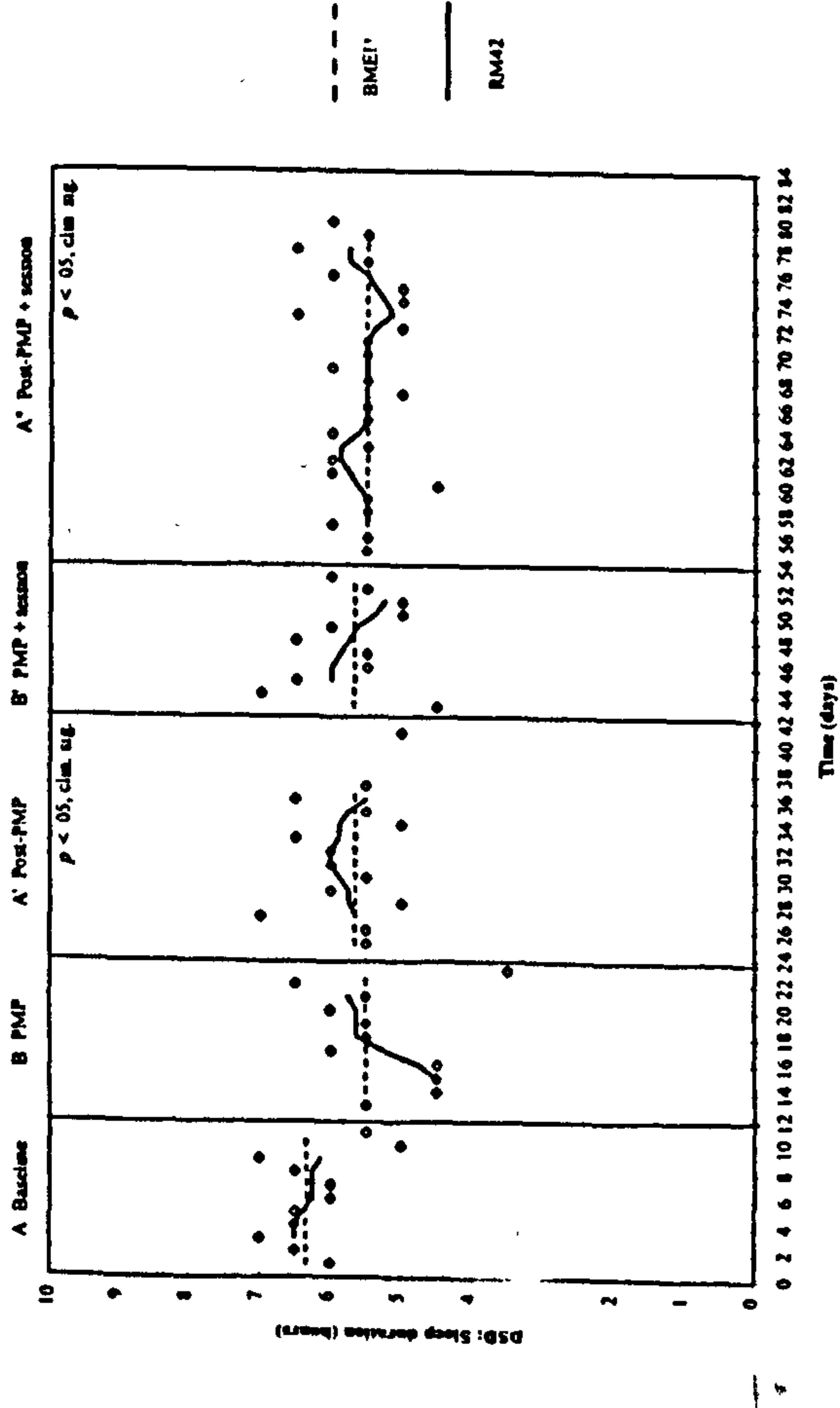
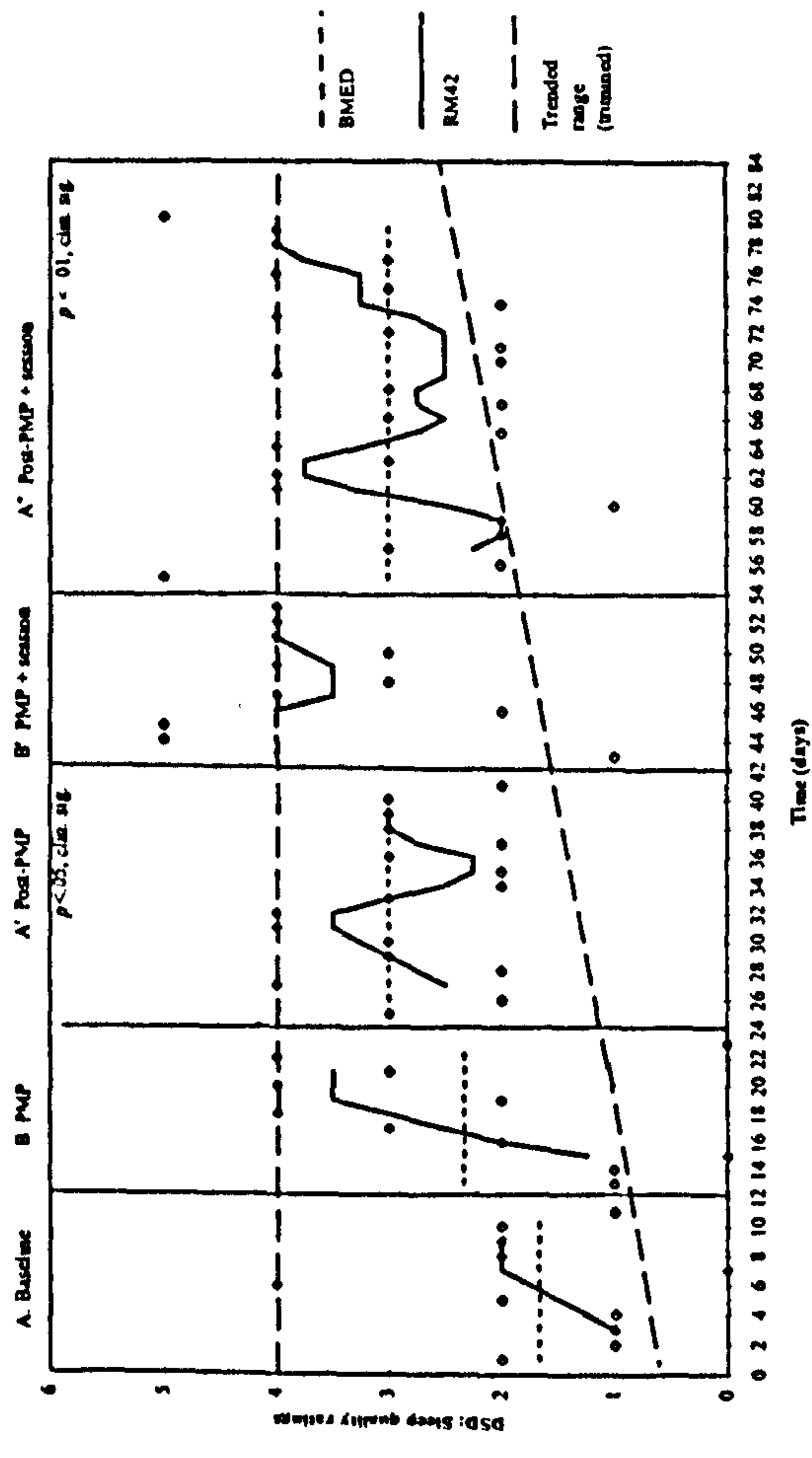
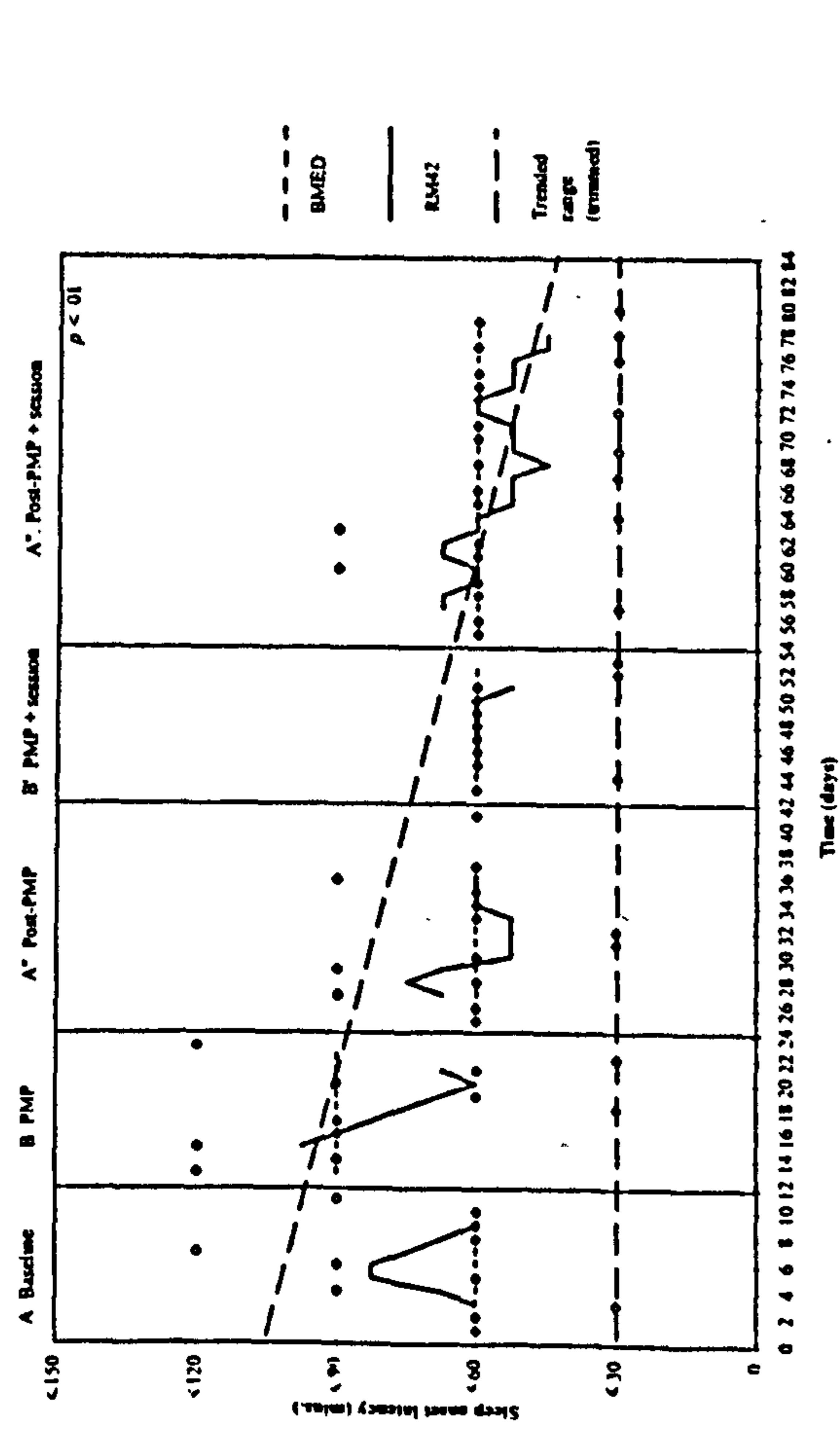


Figure 1. Participant 1: Changes in sleep diary measures across experimental phases. Note. P1 described sleep disturbance due to influenza during phase A'.





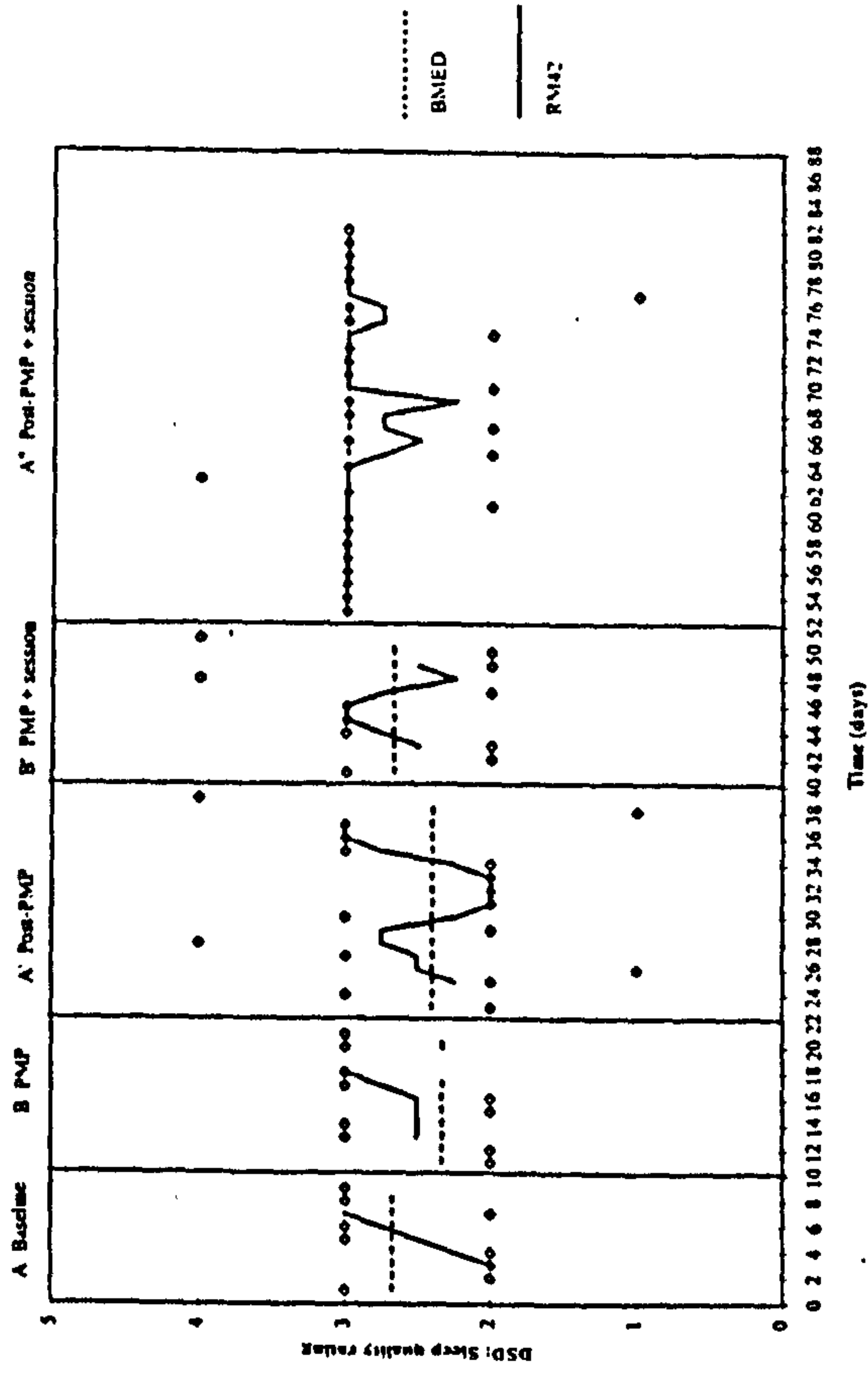
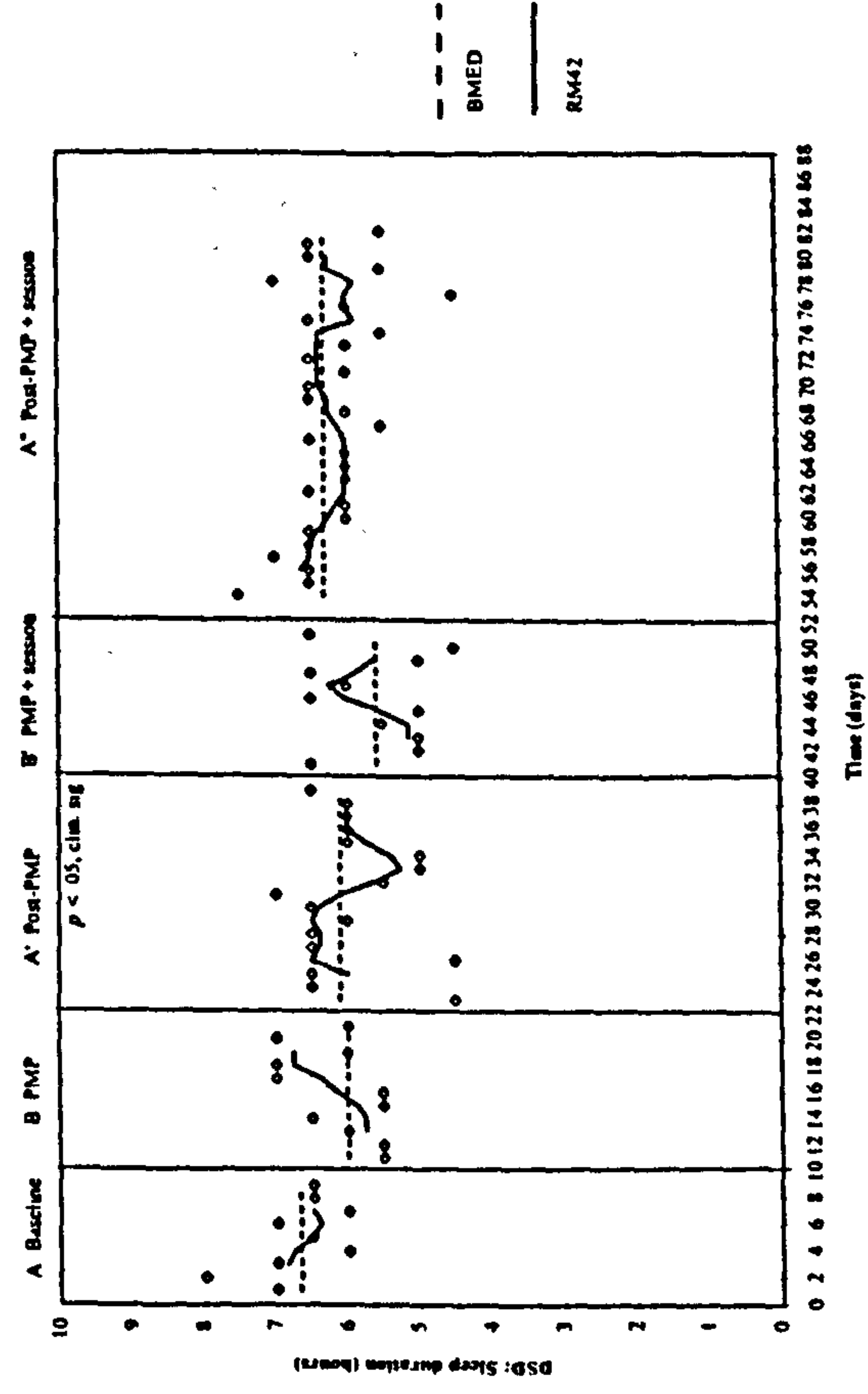
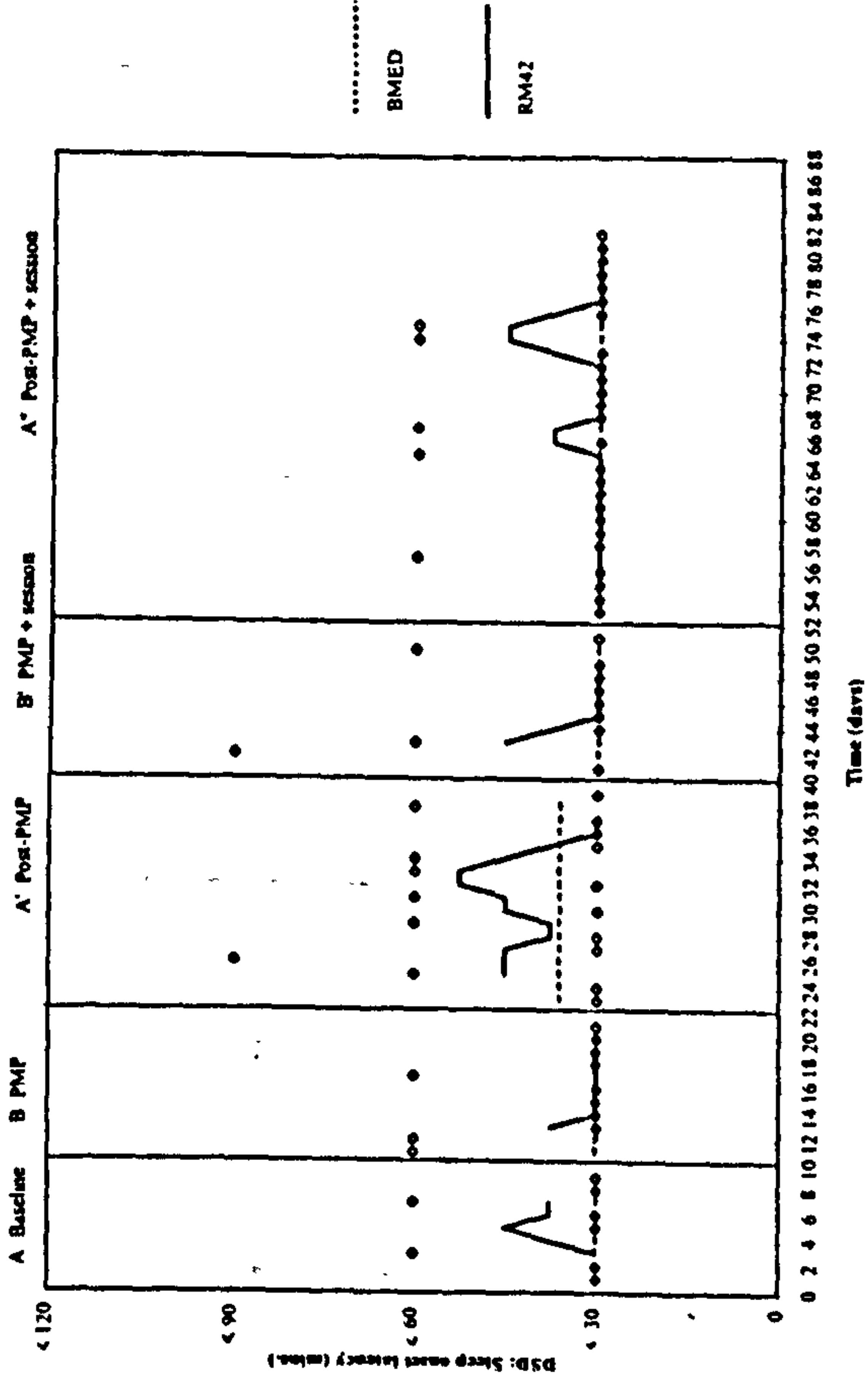


Figure 2. Participant 2: Changes in sleep diary measures across experimental phases. Note. P2 commenced a reduction plan for her use of sleep related medication at phase A'.

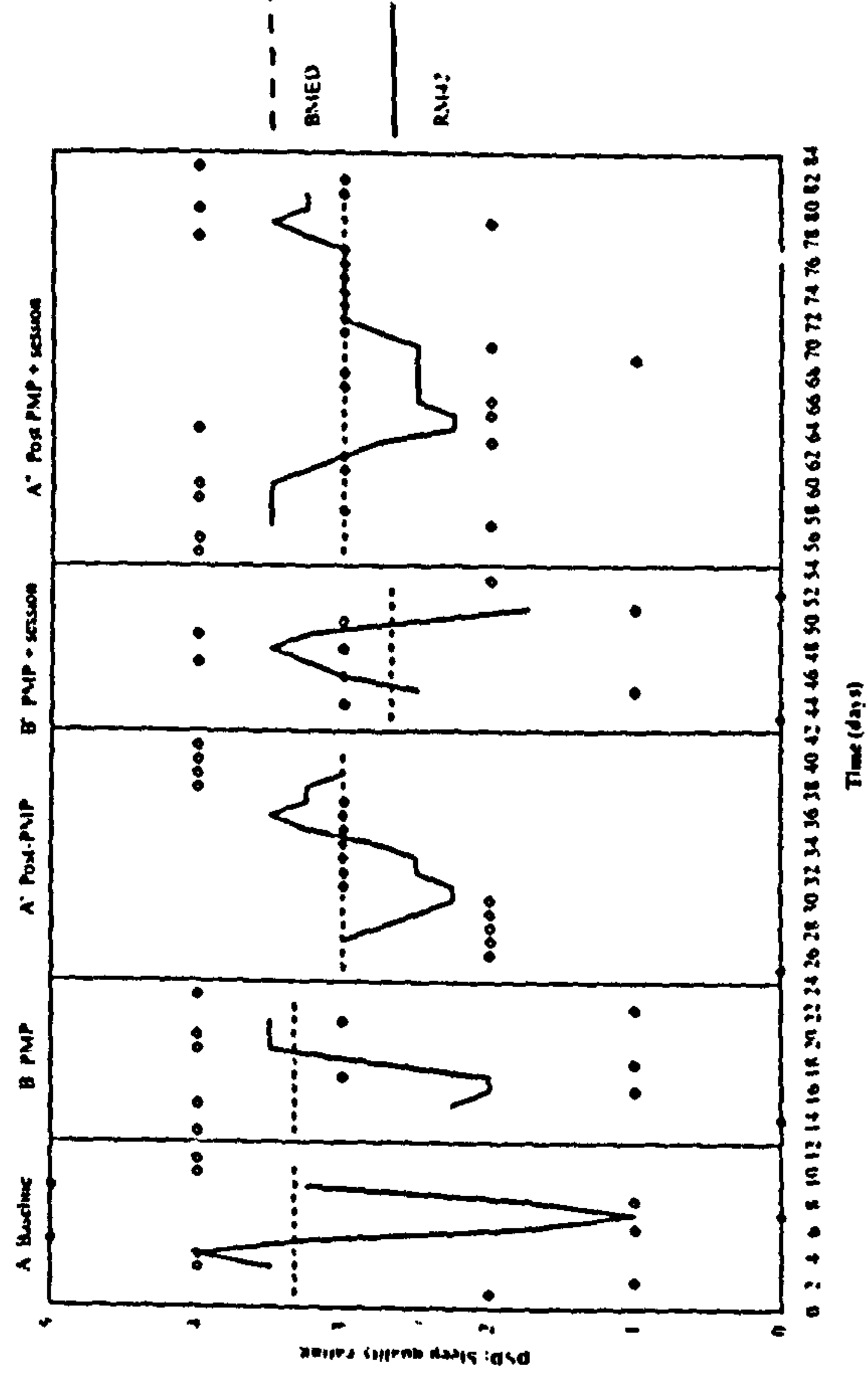
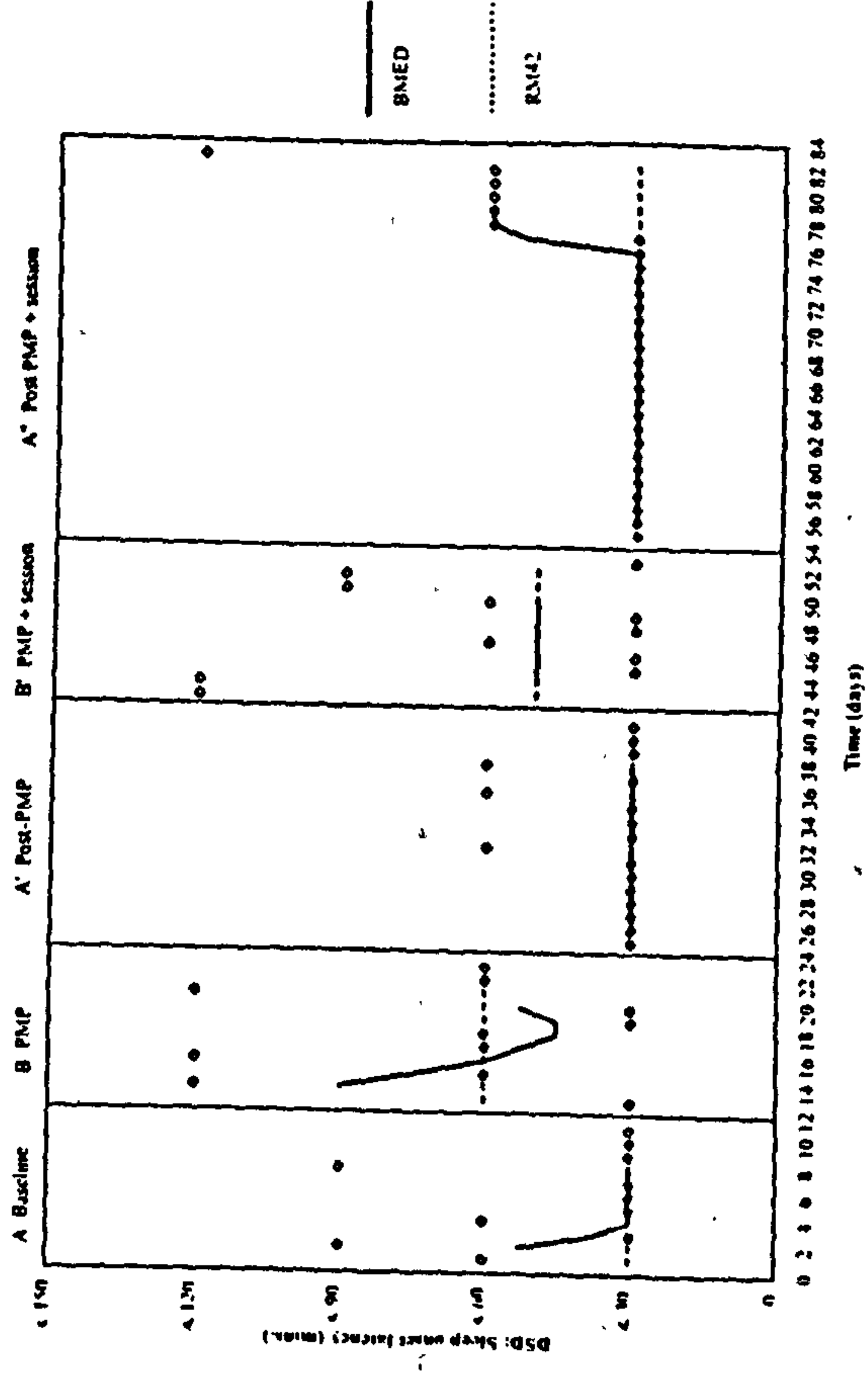
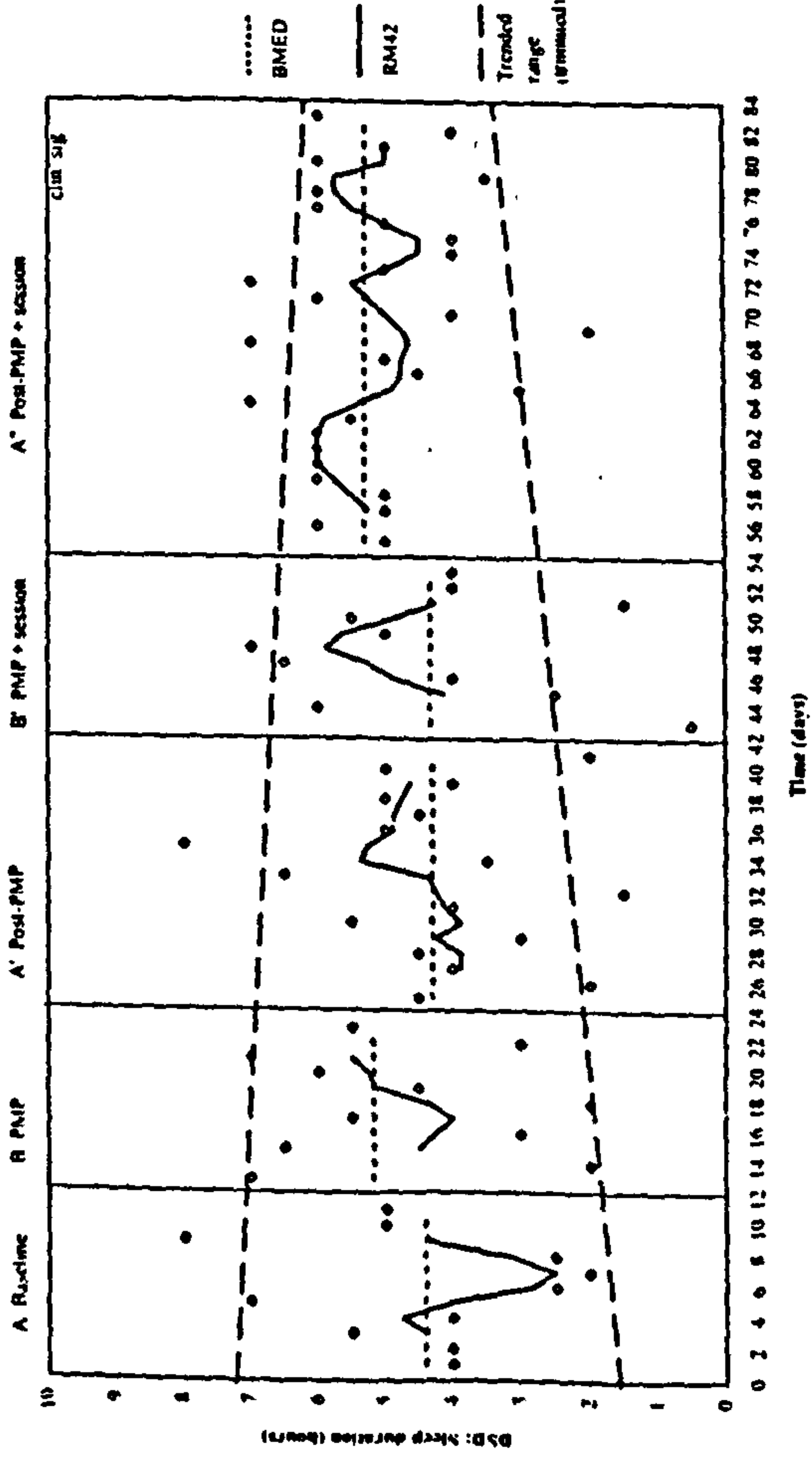


Figure 3. Participant 4: Changes in sleep diary measures across experimental phases. Note. P4 described sleep disturbance due to noise in the PMP accommodation during phases B and B'.

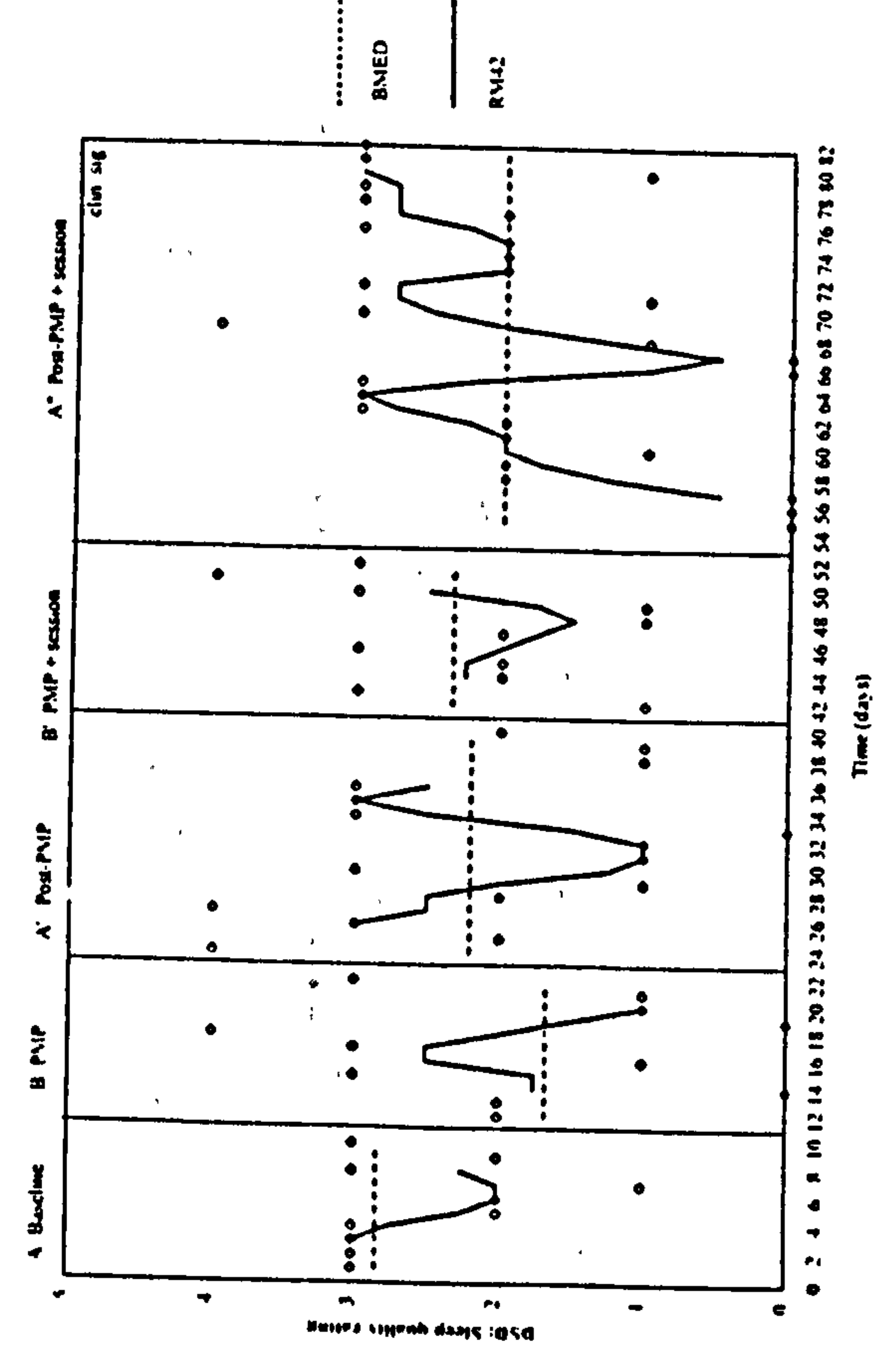
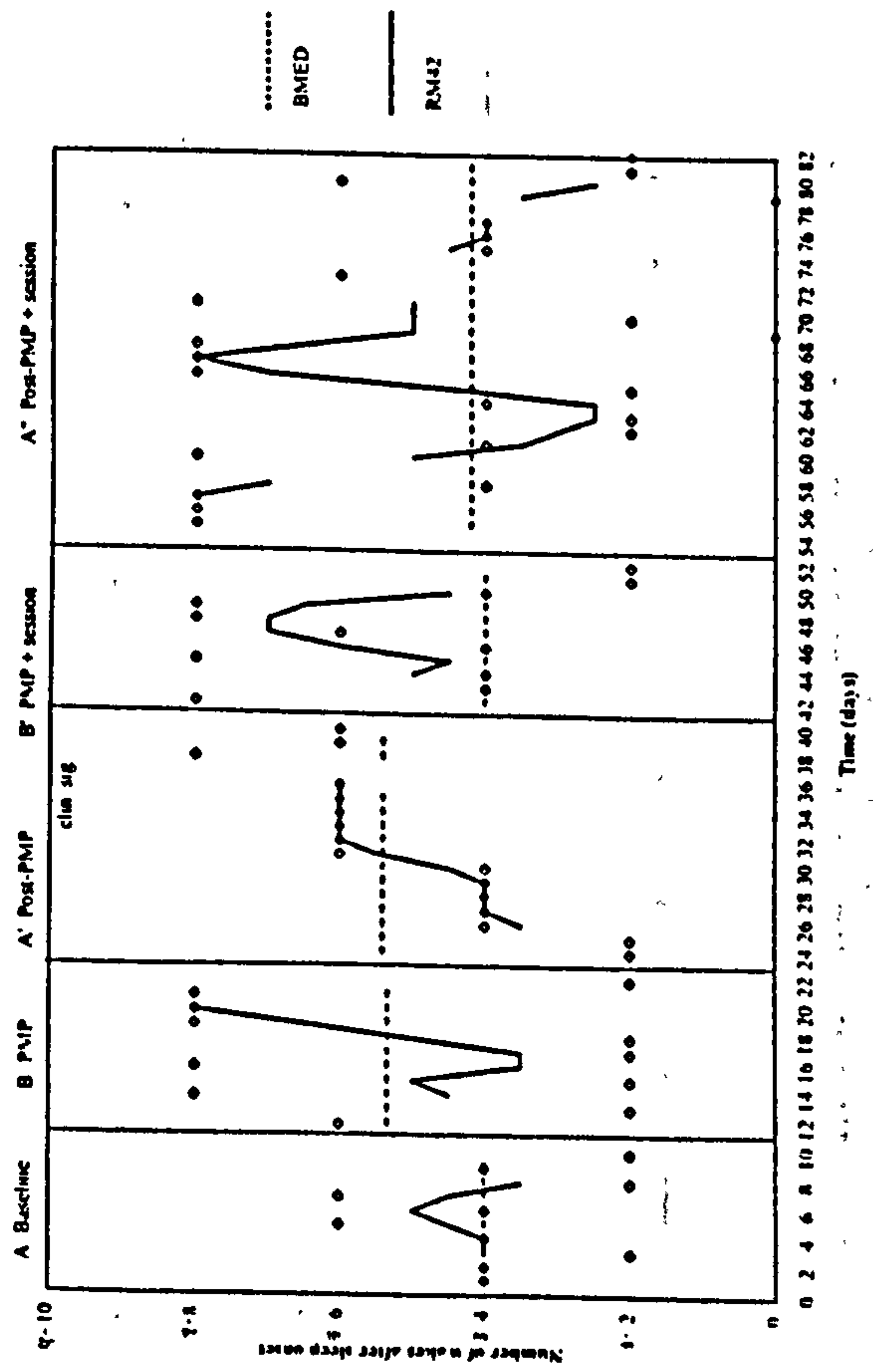
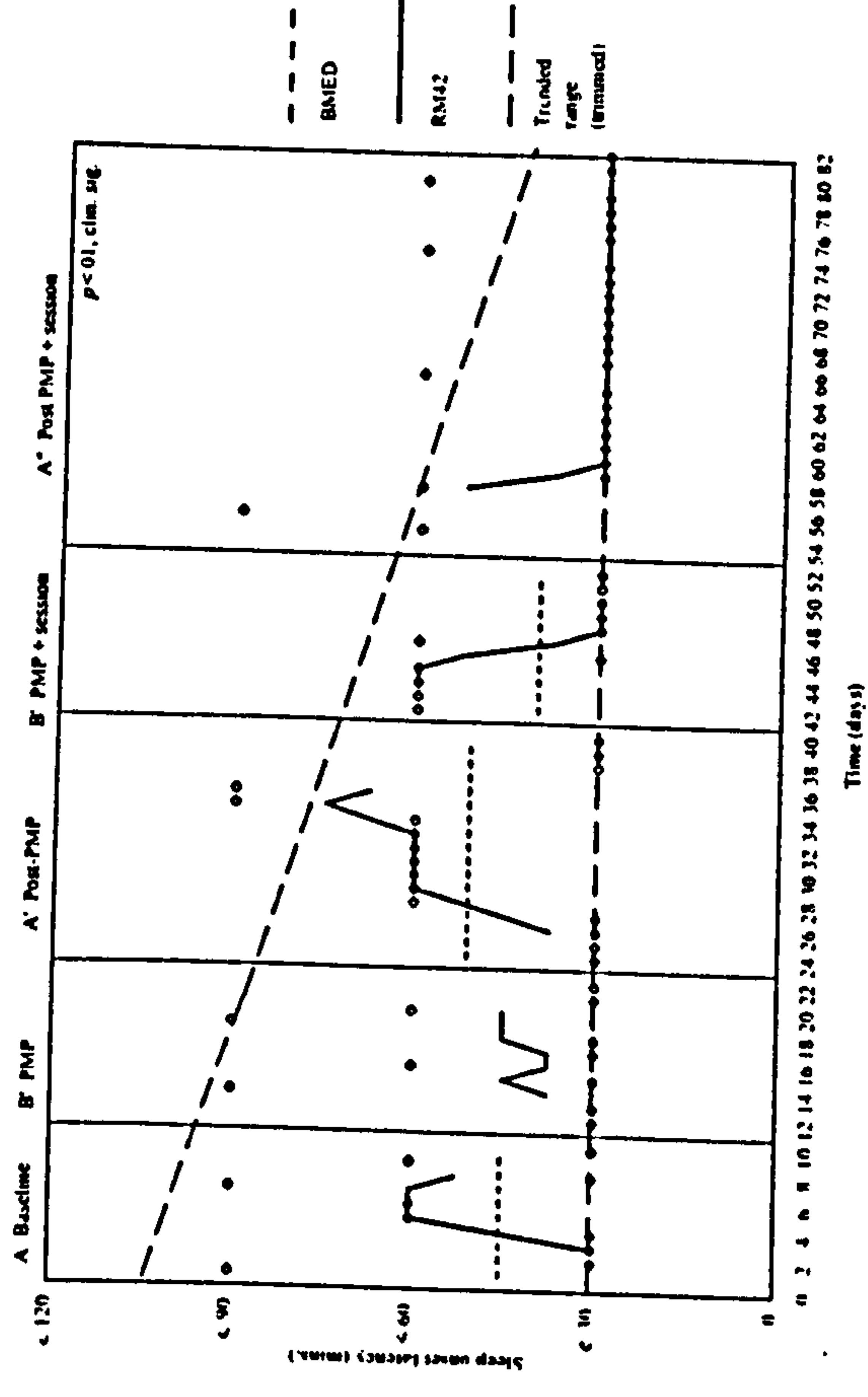
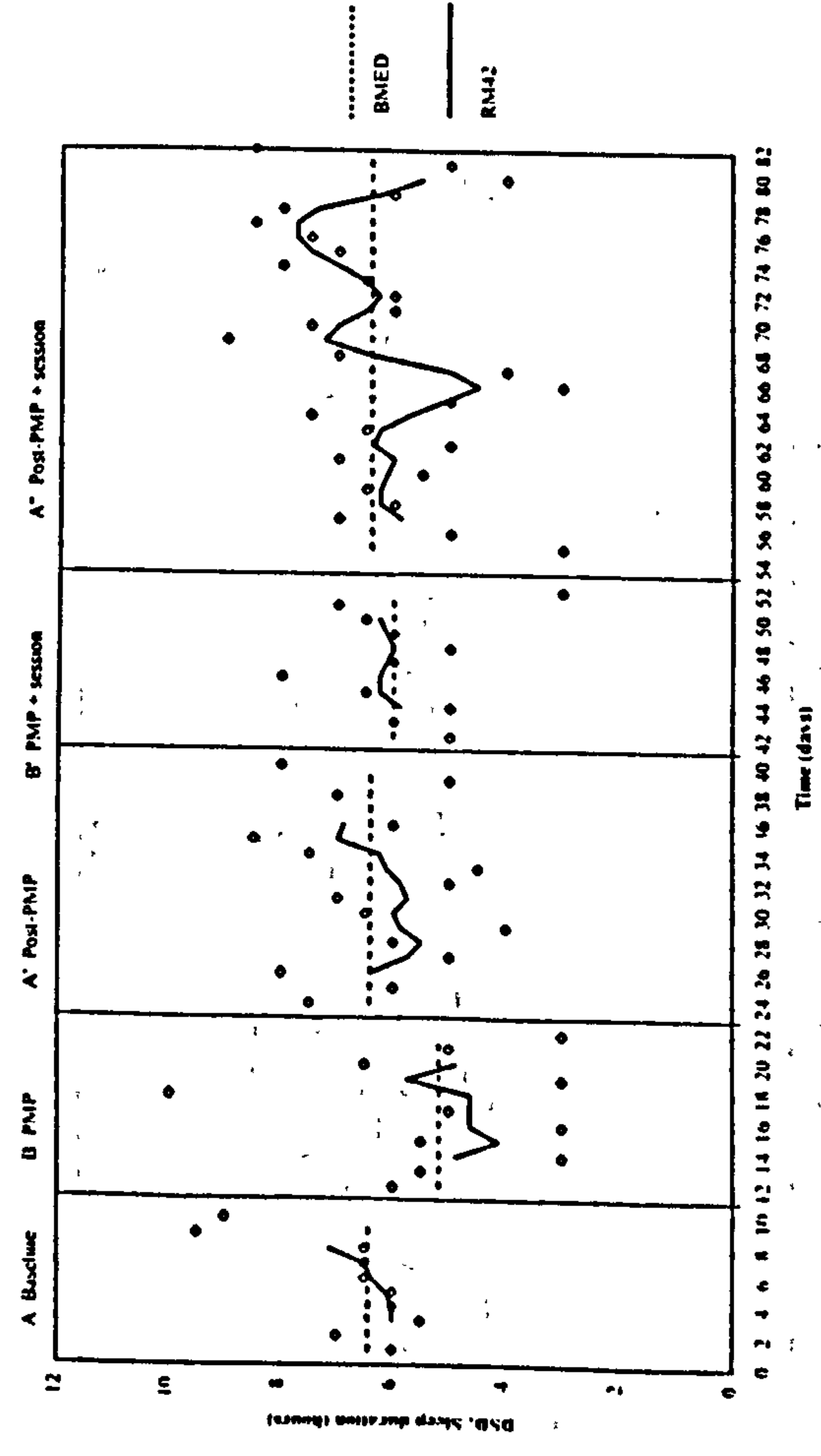


Figure 4. Participant 6: Changes in sleep diary measures across experimental phases.

Note. P6 described asthma symptoms associated with the bedclothes of the PMP accommodation during phases B and A', and a series of several days of increased pain during phase A''.

P6 ceased her use of anitriptyline at phase B.



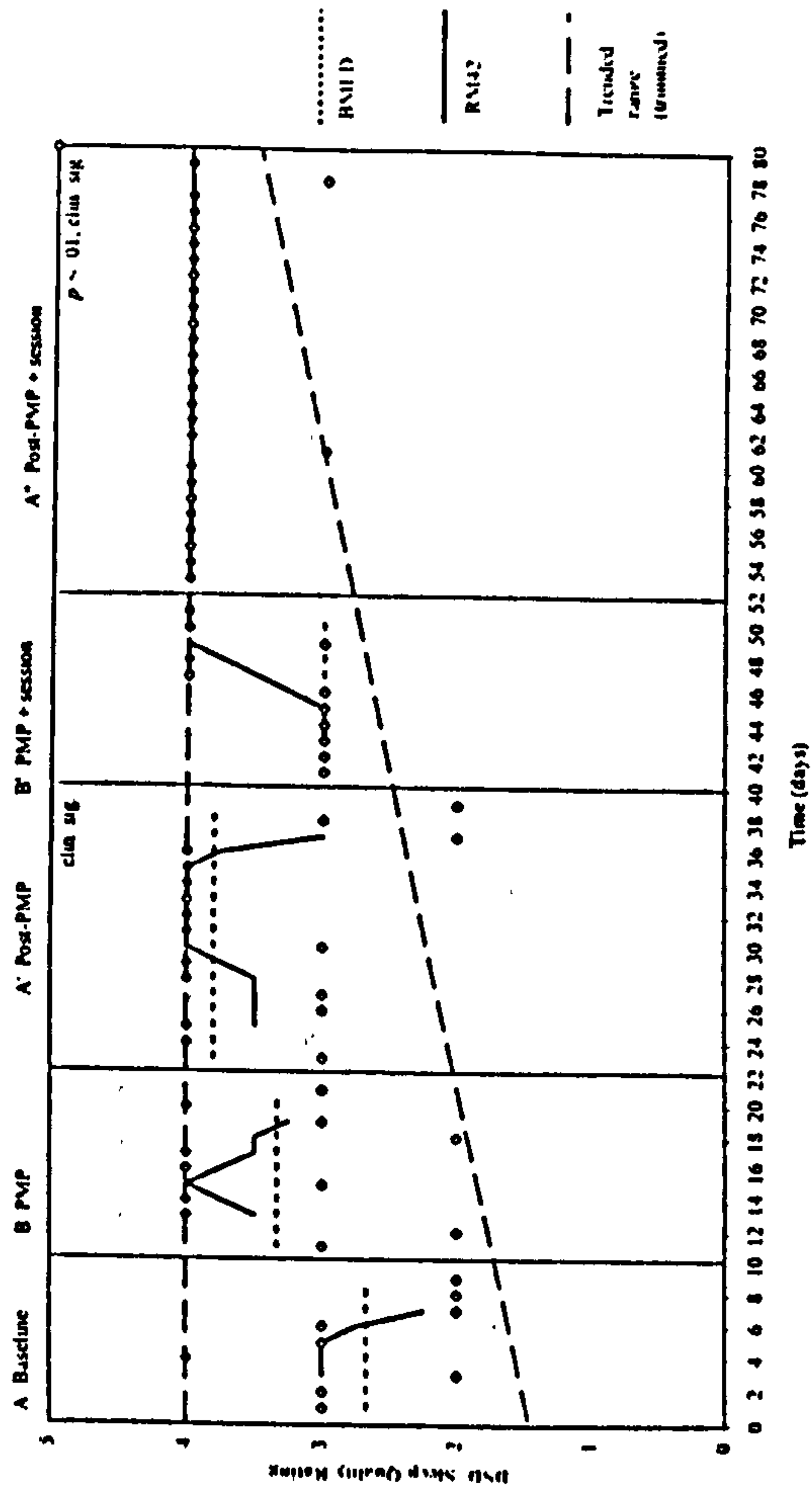
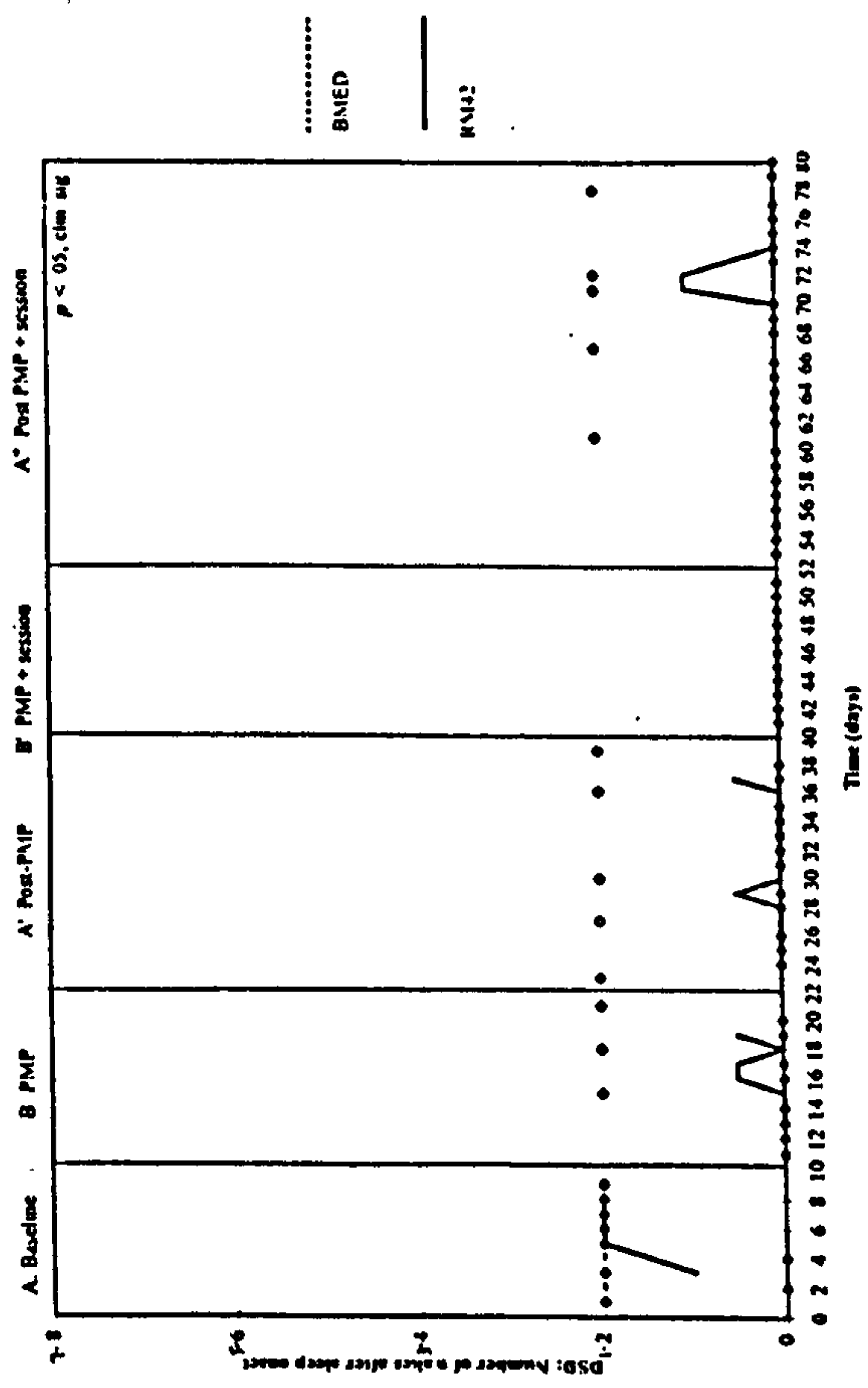
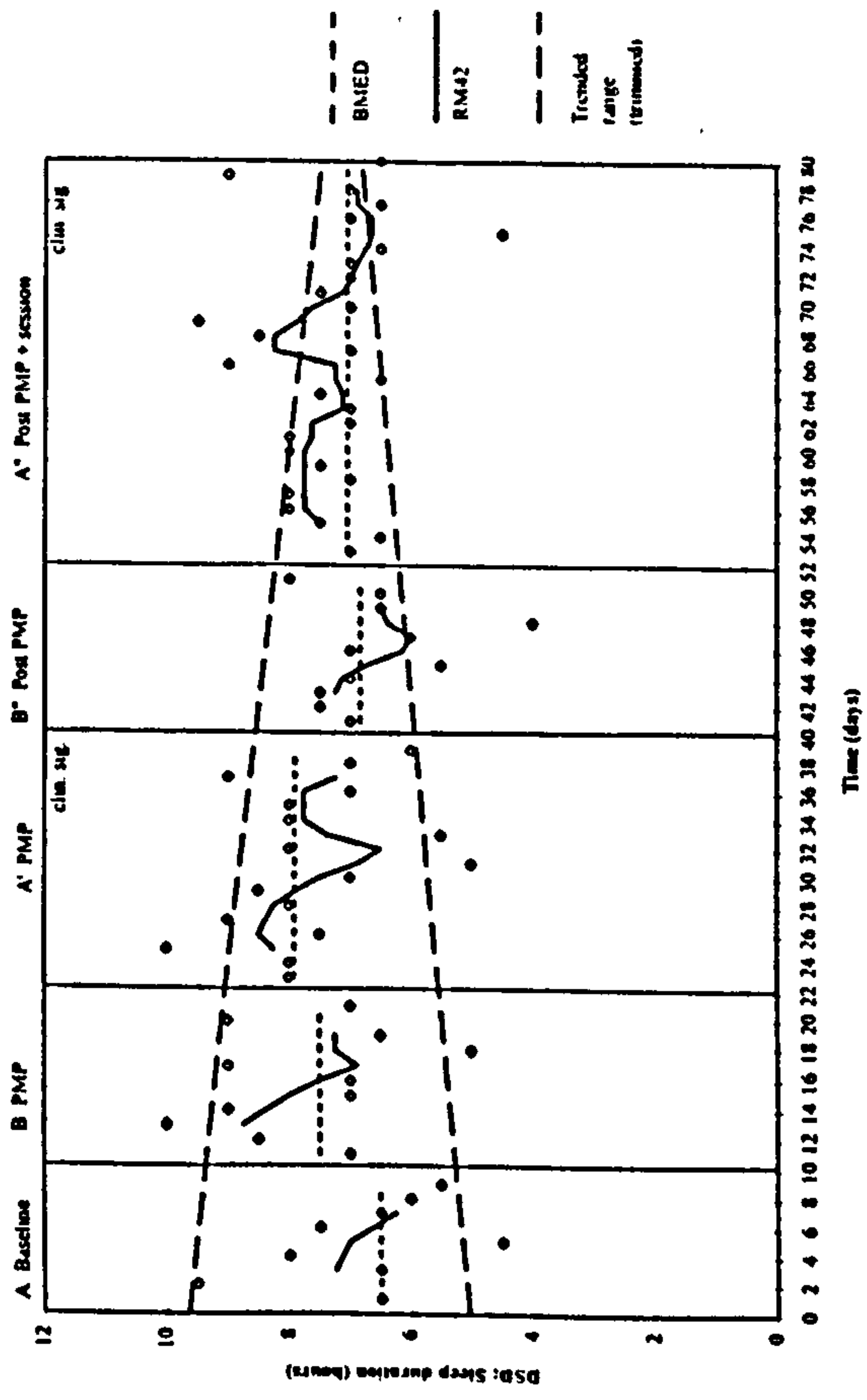


Figure 5. Participant 8: Changes in sleep diary measures across experimental phases.

**Sleep questionnaires and rating scales.**

**Table 2. Sleep disturbance, distress and self-efficacy scores at pre, post-treatment and follow-up assessment**

P No	Sleep Disturbance PSQI (0-21)			Sleep Distress DNRS (0-5)			Sleep Self-Efficacy SENRS (0-5)		
	Pre	Post	F-Up	Pre	Post	F-Up	Pre	Post	F-Up
P1	16	14	14	3	3	3	4	4	4
P2	13	12	12	/	(2)	(2)	/	(3)	(3)
P3	13	9+	9+	2	1	0+	4	5	5
P4	12	17	11	4	3	2+	4	3	3
P5	15	9+	/	/	(1)	/	/	(4)	/
P6	17	12	14	/	(1)	(3)	/	(5)	(1)
P7	16	11+	11+	4	0+	3	5	5	5
P8	8	2+	2+	0	0	0	3	5+	5+
M	13.75	10.75	10.43 *	2.6	1.4	1.6	4	4.4	4.4
SD	2.92	4.4	4.12	1.5	1.52	1.52	0.63	2.3	0.89

\*  $p < .05$ ; + meets criteria for clinical significance; / missing data  
Note. Figures in brackets were not included in calculations. Pre 7-10 days before start of PMP (beginning of phase A); Post last day of PMP (end of phase B'); F-Up one month after PMP (end of phase A'').

As a group, participants' scores on the PSQI were significantly improved at follow-up compared with pre-treatment assessment (Wilcoxon Signed Ranks  $Z=2.37$ ,  $p < .05$ , two tailed).

**Sleep Related Medication.**

**Table 3. Participants' use of sleep-related medication over the study phases.**

P No.	PHASE OF STUDY				
	A: Baseline	B: PMP	A': Post-PMP	B': PMP + session	A'':Post-PMP+session
P1	Tylox (8 mg #) nocte Quinine Sulphate 200 mg nocte	8mg nocte 200mgnocte	8 mg nocte 200 mg nocte	8 mg nocte 200 mg nocte	8 mg nocte 200 mg nocte
P2	Amitriptyline 10 mg nocte	10 mg nocte	10mg altern. nights	10 mg altern. nights	10 mg altern. nights +
P3	Amitriptyline 25 mg 1/month	none	none	none	none +
P4	Not taking sleep related medication	-	-	-	-
P5	Not taking sleep related medication	-	-	-	-
P6	Amitriptyline 10 mg nocte	none	none	none	none +
P7	Zimovane 7.5 mg alternate nights	7.5mg nocte	7.5 mg nocte	7.5 mg nocte	7.5 mg altern. nights
P8	Dihydrocodeine (12 mg #) nocte	12 mg nocte	8 mg nocte	8 mg nocte	8 mg nocte +

**Note.** + meets criteria for clinical significance; # converted to opioid equivalent dose.  
A: 7-10 days before start of PMP; B: first two weeks at PMP; A': two weeks returned home; B': second two weeks at PMP; A'': one month after PMP.

Four of the six participants taking sleep related medication had made a reduction after two weeks at the PMP and of these, two had ceased their use of sleep related medication. These changes were maintained after four weeks at the PMP (phase A'').



**PMP Outcome Measures.**

**Table 4. Anxiety, depression, pain self-efficacy and catastrophising scores at pre, post-treatment and follow-up assessment.**

P No	Anxiety HADS (0-21)			Depression HADS (0-21)			Pain Self-Efficacy PSEQ (0-60)			Catast. CSQ (0-36)	
	Pre	Post	F-Up	Pre	Post	F-Up	Pre	Post	F-Up	Pre	F-Up
P1	11	12	13	12	5 +	10	24	27	28	8	0 +
P2	10	8 +	10	6	7	5	35	34	33	5	14
P3	7	7	6	12	8 +	4 +	21	48 +	51 +	18	9
P4	11	10	8 +	10	8	10	24	29	25	13	11
P5	5	6	/	4	5	/	14	/	/	/	/
P6	11	6 +	10	4	3	3	27	28	25	11	10
P7	6	3	7	4	1	1	35	57 +	51 +	14	7
P8	2	1	0	2	0	1	27	58 +	59 +	5	0
M	7.88	6.63	7.71	6.75	4.63 *	4.86 *	25.88	40.14*	31.14	10.57	7.29
SD	3.4	3.54	4.11	4.38	3.07	3.81	6.98	13.83	14.36	5.24	5.41

\*  $p < .05$ ; + meets criteria for clinical significance; / missing data.  
Note. Pre 7-10 days before start of PMP (beginning of phase A); Post last day of PMP (end of phase B); F-Up one month after PMP (end of phase A').

As a group, participants' scores on the depression subscale of the HADS and PSEQ showed significant improvement at post-treatment compared with pre-treatment (Wilcoxon Signed Ranks  $Z = -1.97, p < .05$ ;  $Z = -2.12, p < .05$ ). This improvement was maintained at follow-up for scores on the depression subscale of the HADS (Wilcoxon Signed Ranks  $Z = -2.23, p < .05$ ).

### **4.3 Summary of Outcome for Each Participant (See Table 4a)**

**P1.** After two weeks at the PMP (phase A') P1 made statistically and clinically significant improvements in sleep quality (Kendall's Tau=0.35,  $p<.05$ , two tailed), but a statistically significant deterioration in sleep duration (Kendall's Tau=-0.32,  $p<.05$ ). After four weeks at the PMP (phase A'') P1 made statistically and clinically significant improvements in awakenings and sleep quality, and statistically significant improvements in sleep latency (Kendall's Tau=-0.36,  $p<.01$ , two tailed; Kendall's Tau=0.35,  $p<.01$ , two tailed; Kendall's Tau=-0.30,  $p<.01$ , two tailed). His sleep duration, however, showed a statistically and clinically significant deterioration (Kendall's Tau=-0.32,  $p<.05$ ). Graphical analysis reveals a trend towards decreased variability in sleep latency, awakenings and sleep quality over the course of the study. P1 made a clinically significant improvement in catastrophising (CSQ) at follow-up.

**P2.** P2 made no significant improvements in her sleep over the course of the study. After two weeks at the PMP she commenced a reduction plan for her use of sleep related medication. Over this period (phase A') her sleep duration showed a statistically and clinically significant deterioration compared with baseline (Kendall's Tau=-0.34,  $p<.05$ , two tailed), and graphical analysis also suggests an increase in her sleep latency (although this was not statistically or clinically significant). These changes were not maintained after four weeks at the PMP, however. P2 made a clinically significant improvement in HADS anxiety at post-treatment but this was not maintained at follow-up.

**P3. (Non-completer)** P3 made clinically significant improvements in sleep disturbance (PSQI) at both post-treatment and follow-up, and in sleep distress (DNRS) at follow-up. At both post-treatment and follow-up, he made clinically significant improvements in his scores on the

Table 4a. Summary of outcome and post-treatment comments for all participants.

P	Outcome Measure											
	DUR	SOL	WASO	QUAL	PSQI	DNRS	SENRS	MEDS	HADA	HADD	PSEQ	CSQ
1	++	+	++	++	0	0	0	0	0	0	0	(+)
	The exercise is helping me sleep because I'm tired - I'm sure lack of activity is part of it. The relaxation is great - I imagine I'm an eagle and stretch my arms out.											
2	-/-	0/0	0/0	0/0	0	nc	nc	(+)	0	0	0	0
	It's no better but I expect it will take a while.											
3	nc	nc	nc	nc	(+)	(+)	0	(+)	0	(+)	(+)	0
	I don't worry about not sleeping now. I still sleep badly but it doesn't bother me. Relaxation works a treat! I was in the habit of relaxing but not sleeping. Now I'm learning to relax deeply and sleep. It's a better quality sleep.											
4	0/+	0/0	na	0/0	0	(+)	0	0	(+)	0	0	0
	See Appendix 17 for spontaneously completed thoughts form on intervention. My leg cramps are reducing at night - I'm told that's because of the stretch.											
5	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc	nc
	It's not really any better. It doesn't seem to work.											
6	0/0	++	0/0	0/-	0	nc	0	(+)	0	0	0	0
	I feel better now I've stopped the amitriptyline - better quality of sleep & I'm more alert in the day. Sleep is still poor but I use stretch & relaxation if I cannot sleep. See Appendix 17											
7	nc	nc	nc	nc	(+)	0	0	0	0	0	(+)	0
	I'm not using the collar any more. With pain I've no worry - I'm not scared of my neck any more. Sleep's a better quality. I don't need much. I never have.											
8	0/+	na	++	++	(+)	0	(+)	(+)	0	0	(+)	0
	Rarely now wake during the night, even to go to the loo. A great improvement. I have a better night if I get up earlier, have less sleep & know exactly what I'm doing the following day.											

Note.

DUR: Sleep Diary sleep duration      PSQI: Pittsburgh Sleep Quality Index (sleep disturbance)      HADA: Hospital Anxiety & Depression Scale: Anxiety      0: no change  
SOL: Sleep Diary sleep onset latency      DNRS: Sleep Distress Numerical Rating Scale      HADD: Hospital Anxiety & Depression Scale: Depression      (-): clinically significant deterioration  
WASO: Sleep Diary wakes after sleep onset      SENRS: Sleep Self-Efficacy Numerical Rating Scale      PSEQ: Pain Self-Efficacy Questionnaire      /: statistically/clinically significant change  
CSQ: Coping Strategies Questionnaire (catastrophising)      nc: non-completer      na: not applicable



HADS depression subscale and pain self efficacy (PSEQ). Although at pre-treatment he was only using amitriptyline to help him sleep on a monthly basis, P3 had not used any amitriptyline over the 10 week duration of the study.

**P4.** No statistically significant improvements were made by P4 on any of the sleep diary measures. After four weeks at the PMP, however, he made a clinically significant improvement in sleep duration (BMED increase of 54 minutes) and graphical analysis reveals a trend towards decreased variability in the amount of sleep he obtained each night. This improvement was made with no corresponding deterioration in sleep latency (Prior to the individual session P4 was going to bed late in order to expedite sleep onset. He commenced earlier bed-times during phase A"). At follow-up, P4 made clinically significant improvements in sleep distress (DNRS), and on the HADS anxiety scale.

**P5.** (Non-completer) At post-treatment assessment, P5 made a clinically significant improvement in sleep disturbance (PSQI).

**P6.** P6 ceased her use of amitriptyline which she had been using to get to sleep. After four weeks at the PMP she made statistically and clinically significant improvements in sleep latency (Kendall's Tau=-0.32,  $p<.01$ , two tailed), and graphical analysis suggests a corresponding decrease in variability in these scores. A clinically significant increase in awakenings after two weeks at the PMP (which she attributed to an increase in asthma symptoms) and decrease in sleep quality after four weeks at the PMP was found, however, and at follow-up assessment, her scores on the DNRS and SENRS indicate clinically significant deteriorations in sleep distress and self-efficacy, compared with post-treatment assessment. Her score on the HADS

anxiety subscale showed a clinically significant improvement at post-treatment but this was not maintained at follow-up.

**P7. (Non-completer)** P7 made clinically significant improvements in sleep disturbance (PSQI) at both post-treatment and follow-up, and in sleep distress (DNRS) at post-treatment (although this was not maintained at follow-up). At both post-treatment and follow-up, P7 made clinically significant improvement in pain self-efficacy (PSEQ). She increased her use of sleep related medication during phases B, A' and B'' of the study but after four weeks at the PMP this had returned to baseline levels.

**P8.** P8 made clinically significant improvements in sleep duration and quality after two weeks at the PMP, and statistically and clinically significant improvements in awakenings and sleep quality (Kendall's Tau=-0.24,  $p<.05$ ; Kendall's Tau=0.45,  $p<.01$ , two tailed), and a clinically significant improvement in sleep duration, after four weeks. Graphical analysis suggests a trend towards decreased variability in sleep duration and quality over the course of the study. P8 made clinically significant improvements in sleep disturbance (PSQI), sleep self-efficacy (SENRS) and pain self-efficacy (PSEQ) at both post-treatment and follow-up.

All participants were sent feedback concerning their progress on the study (Appendix 20).

#### **4.4 Changes During Residency at PMP**

Although analysis of the efficacy of treatment focusses on phases A, A' and A'' of the study, graphical analysis of Figures 1-5 reveals changes for some participants that took place during the first and second two weeks of the PMP (phases B and B'). P4 showed a statistically and

clinically significant deterioration in sleep latency during the second two weeks of the PMP (Kendall's Tau=.36;  $p<.05$ , two tailed). Clinically significant deteriorations in sleep duration are found for P1, P2 and P6, in sleep latency for P1 and P4 and in awakenings and sleep quality for P6 during the first two weeks of the PMP. P8, however, makes clinically significant improvements in awakenings and sleep quality during the first two weeks.

## **PART II**

**The psychological processes which determine and maintain the relationship between participants' experience of chronic pain and insomnia, and their response to treatment.**

### **4.5 Part II Participants: Transcript data**

Five main themes emerged from the analysis of the transcript data: disruption of sleep by pain; complaints of arousal preventing sleep; the dilemma of using or not using external means to aid sleep; failure of problem solving attempts; and lack of pre-pain satisfying sleep. In accordance with the recommendation that verbatim evidence is presented to enable the reader to interrogate the interpretation (Smith, 1996a), participant quotations are used to illustrate the themes and sub-themes. See Table 5.



Table 5. Transcript data themes and sub-themes with example participant quotations.

THEMES & SUB-THEMES	EXAMPLE PARTICIPANT QUOTATIONS
DISRUPTION OF SLEEP BY PAIN Pain means you are unable to find a comfortable position	P13 "I have real bad problems sleeping on my right side. If I lay on the back of my head, like that, if it falls to the side ... when I wake up I'm always on my right side ... and I need to turn back because of my neck. ... because I'm flat, and I would push the pillows around my head and neck, to keep it straight, and that's a fairly comfortable position for me. But if they say go a bit flat or something, then my head will drop. And it ... things like that wake me up."
Pain means you wake up or cannot get off to sleep	P9 "The problem is that as your body naturally turns over in the night, because my body hurts me, that pain as I try to roll over will wake me up. Normally only for a few seconds. It's a split second sometimes, or most of the time. The problem is - that <i>can</i> happen lots of times throughout the night - like the first night here I stayed counting after twenty times, so it means that you never ever have a good night's sleep."
COMPLAINTS OF AROUSAL You cannot sleep because thoughts are going through your mind (cognitive arousal)	P8 "I've found it extremely difficult to 'switch off': all sorts of things are going through my brain." P11 "I wake up, say I might have a tablet, I'm awake and I look at the clock you know. And then you're trying to get to sleep, and your brain box is going all over the place, and thinking about this, thinking about that. I mean a lot of people have said try counting ... I mean it's probably good but what I find is that your mind is wandering, wandering."
You cannot sleep because you get frustrated and irritated (emotional arousal)	P10 "[I feel] drained, annoyed - very annoyed ... You just wish you could sleep, get some rest. Your eyes want to close, you get too tired - overtired. And even though you want to, because of the pain you can't sleep."
DILEMMA OF USING/NOT USING EXTERNAL HELP. Sleeping tablets help	P5 "About four weeks ago I was in hospital for ten days because of my back and they gave me sleeping tablets... and they were incredible... you lay there and you think well these aren't working.. and all of a sudden you wake up and there's a cup of tea and its morning"
They help but I'd rather do without	P15 "I don't think I would go to sleep at all without the tablets. Because I have tried cutting down on them. Because I don't like taking all these tablets. But, no chance." P7 "If I leave it [the neck collar] off I twist and turn in the night and then my head is loose, the Doctor says. I don't know, um goes loose or something meaning I could throw the spine out or something? And I do, I try hard not to wear it."
The disadvantages out weigh the advantages	P3 "I don't like the effects of amitriptyline. It tends to fog my head ... I spent about eighteen months with my brain wrapped in cotton wool and I had enough of it ... I'd rather put up with a bit more pain ... I feel it more but I'm able to hold conversations and generally get on with my life as much as I'm capable of."
FAILURE OF PROBLEM SOLVING ATTEMPTS. Nothing helps	P1 "I've tried more clothes on the bed, less clothes on the bed, every way - you know - pyjamas, this that and the other - I've tried every thing ... nothing's benefited me in the long run ... I can't do it - you know even with alcohol and things like that. I've tried having a drink, I've tried having milk, I've tried having this. I've tried having the other - but nothing.."
It doesn't make sense	P8 "I've tried to rationalise it and I can't ... its bizarre I think, absolutely bizarre"
You just have to resign yourself to it	P2 "I think I've got so used to it over the years I don't know anything different now"
REGRET OVER LACK OF PRE-PAIN SATISFYING SLEEP Sleep gives you relief from the pain.	P6 "Usually once you sleep, you're pain free for a while. Well no that's not exactly true is it but you're more relieved and you've got less pain when you're asleep." P15 "But you know towards the end of the day, I just can't wait to take those tablets because I know I'm going to be out of pain for a few hours."
Poor sleep has negative effects on self	P9 "Out of everything associated with my pain, my sleep is my biggest problem. Because I do feel if I slept, I'd feel refreshed, and I could cope with the rest of it"
Poor sleep has negative effects on your family	P7 "You do, you get ratty, you get moody. I take it out on other people sometimes, like family - I heard you! Why couldn't you have kept quiet while I was asleep?" - you know? Or the 'phone will go and I think 'oh no' - I'm resting or something (laughs). You know, I'd be silly if I said I don't get annoyed or upset about it all."
Comparisons with the past	P14 "I mean if you have had a bad night, you fall asleep watching telly in the evening after tea, then you can forget sleep for a long while. In normal life that ain't a problem. I mean in normal life, I never had a sleep problem before."
Comparisons with other people	P9 "People wake up and they say 'God I feel good' - well that never happens."
Wish to return to that state	P1 "I will lie there keep lifting my head up and looking at the clock and you know I just - I hate night-time basically - I hate the night-times ... but to make it sort of go away would be ... would be a complete release ... It would be heaven you know just to feel the difference."

4.6 Post-Treatment Comments (Part I Participants only)

Two main themes emerged from the analysis of Part I participants' post-treatment comments: success of problem solving attempts and redefinition of the problem. See Table 6.

**Table 6. Post-treatment data themes and sub-themes with example participant quotations.**

THEMES	EXAMPLE PARTICIPANT QUOTATIONS
<b>SUCCESS OF PROBLEM SOLVING ATTEMPTS</b> I understand why it happens and what I can do to help	P8 "I've realised I have a better night if I get up earlier, have less sleep & know exactly what I'm doing the following day." P3 "The relaxation works a treat! Before, I was in the habit of relaxing but not sleeping. Now I'm learning to relax deeply & get to sleep."
Nothing helps	P5 "It's not really any better. It doesn't seem to work."
<b>REDEFINITION OF THE PROBLEM</b> The problem persists but I am not distressed about it	P3 "I don't worry about not sleeping now. I still sleep badly but it doesn't bother me "

See Table 1 for further examples of participants' post-treatment comments.

## DISCUSSION

### **PART I**

**The effect of attending a PMP, and receiving an additional individual cognitive-behavioural intervention for insomnia, on (a) the sleep pattern and quality, and (b) the level of distress and ability to cope with poor sleep, of individual patients who have chronic pain and complain of problems in sleeping.**

#### **5.1 Outcome**

The results of the current study demonstrate the extent of insomnia associated with chronic pain. Each participant's score on the PSQI fell above the cut-off score of five for distinguishing good from poor sleepers (Buysse *et al.* 1989), and was comparable with the results of other studies using this questionnaire in chronic pain populations (Wilson *et al.*, 1998).

Two of the five participants who completed the sleep diaries had made statistically and/or clinically significant improvements in two parameters of their sleep after two weeks stay on the programme (i.e. phase A'). There is an indication therefore that a minority of participants might achieve changes in their sleep pattern and quality after two weeks of PMP treatment. However, the results are not replicated across all five completers and cannot therefore be generalised to all patients receiving the same intervention.

Four of the five completers made statistically and/or clinically significant improvements in at least one sleep diary measure after four weeks at the PMP. All of the three non-completers made clinically significant improvements in sleep disturbance (PSQI) at follow-up. These changes were accompanied by clinically significant change in at least one of the PMP outcome measures for the majority of participants. Four of the six participants taking sleep-related



medication had made reductions in their medication at follow-up with two having ceased its use completely. As a group, participants showed a statistically significant improvement in sleep disturbance at follow-up. These results are promising concerning the efficacy of the PMP and individual cognitive behavioural intervention in improving sleep pattern and quality.

Of the five participants who had been administered the DNRS and SENRS, at follow-up two had made clinically significant decreases in sleep distress, and one a clinically significant increase in sleep self-efficacy. The proportion of participants making changes on these parameters was relatively low, and the efficacy of the intervention in effecting change in these domains would not therefore seem to be supported.

Inspection of sleep diary data for the period where participants were first resident on the PMP (phase B) reveals that four of the five completers experienced a clinically significant deterioration in at least one parameter of their sleep during this phase. Changes in two variables had taken place at this time: introduction of the intervention and alteration in sleep environment. It is therefore not possible to identify which factor is responsible for these changes but it is noted that two completers commented on difficulties associated with sleeping in the PMP accommodation (see figures 3 and 4). Other explanations might include anxiety associated with admission and initial increased pain on commencing the exercise regime and coping with the demands of a new environment.

## **5.2 Critical Review**

When considering the joint effect of attending a PMP and receiving an additional individual cognitive-behavioural intervention for insomnia on patients' sleep pattern and quality, the

results at follow-up seem promising. Those changes in sleep parameters that were effected appear particularly notable when considering the severity of participants' sleep disturbance, the chronicity of their pain and level of distress and disability. As participants' pain problems persisted over the duration of the study, the results may offer some support to the proposal that factors other than the experience of a painful medical condition are important in understanding the aetiology of sleep disturbance in this population (Hyypä & Kronholm, 1989; Mitrer *et al.*, 1991). They are consistent with the results of previous studies evaluating the efficacy of psychological interventions for people with insomnia secondary to chronic pain (Varni, 1980; Cannici *et al.*, 1983; Treves, 1993), but the degree of change on the sleep diaries is not as substantial as that reported in other single case studies conducted on this population (cf. Morin *et al.*, 1989; Morin *et al.*, 1990).

In considering the sleep diary data, it is important to note that the results are not replicated across all completers, however, and the number of sleep diary measures in which completers showed an improvement at follow-up varied. In some instances completers experienced a clinically significant deterioration in one sleep diary measure whilst experiencing improvements in others. Additionally, it is not clear whether the improvements made by completers were in the sleep parameters in which they most wanted change. It would be premature to generalise from these results that the same intervention would be effective for all patients. There were also a number of flaws in the design of the study that limit the conclusions that can be drawn.

**Variability in Response.** Hersen & Barlow (1976) suggest that the investigator must examine reasons for lack of client generality in a replication series where mixed results are obtained. P2 made no significant improvements in sleep over the duration of the study and the results of P6

were mixed. The presence of other difficulties may have contributed to their response to treatment. During her time at the PMP, P2 disclosed a bereavement which following clinical assessment, was felt to be unresolved and resulting in depressed mood. Depression is widely recognised to be associated with poor sleep (Morin & Ware, 1996) and it is possible that this mood state compromised P2's response to the intervention. Ideally this would have been identified, and successfully treated prior to the commencement of an intervention for insomnia (Lichstein & Riedel, 1994), but P2 described having being very keen to conceal the extent of her distress at both screening and pre-treatment.

A variety of factors may have been responsible for P6's mixed response to treatment: firstly, she experienced a number of difficulties over the duration of the study which would be likely to result in additional sleep disturbance (an increase in asthma symptoms, a series of days of increased pain and a road traffic accident on the day of her follow-up assessment); secondly, it is noted that her wakefulness at night was as a result of another medical condition rather than chronic pain; and finally, her cessation of amitriptyline, although having no effect on sleep latency, may have resulted in withdrawal effects similar to those reported for benzodiazepines, which impaired the maintenance of her sleep over the duration of the study (Morin, Colecchi, Ling & Sood, 1995). A longer follow-up period would demonstrate whether these effects were maintained. (A reduction in amitriptyline may also have been a factor influencing P2's progress.)

**Measures of distress and self-efficacy.** With regards to the low proportion of participants achieving changes on measures of sleep distress and self-efficacy, this may be more a function of the scales used to assess these constructs, rather than an indication that the intervention was



not effective in reducing participant distress and increasing self-efficacy. The reliability of these scales was not assessed prior to their use in the study, which is a serious limitation in a study using a repeated measures design. Their validity is also questionable.

Other measures which might have been used to assess sleep distress and self-efficacy include the extended version of the Sleep Disturbance Questionnaire (Coyle & Watts, 1991) and the Self-Efficacy Scale (Lacks, 1987). The former, however, is not specifically focussed on distress associated with poor sleep, and there are no normative data on the latter. In addition, on a programme where patients already complete a battery of at least 10 different outcome measures, the effect on patients (and completion rates) of two additional questionnaires comprising of 30 and seven individual items respectively, had to be taken into consideration.

Although not formally an outcome measure, in considering the efficacy of the intervention in reducing sleep distress, and improving sleep self-efficacy, another source of information available in the current study is participants' post-treatment comments.

**Study design.** To analyse treatment outcome, baseline data were compared with data collected during phases A' and A'' when participants had received the intervention(s) and returned to their usual sleep environment. This was carried out because during phases B and B' a second variable was changed (sleep environment) at the time of manipulation of the independent variable (i.e. the intervention) thus complicating analysis of changes in the dependent variables (sleep diary measures). In effect, therefore, although there were five phases in the current study (ABA'B'A''), the type of single case design used was a form of the AB design, where the treatment phase is compared with baseline, with no reversal phase.

The AB design is described as the least satisfactory of all the single case designs because it consists only of comparing the baseline with the intervention phase (Peck, 1985; Long & Hollin, 1995; Morley, 1996). It is not therefore clear whether changes arise as a result of the intervention or due to other uncontrolled events. A phase of withdrawal of the intervention is typically recommended to decide whether the treatment was responsible for change in the data. This was not thought to be either possible or ethical in the current study, however, because participants had already commenced using self-management strategies and were being actively encouraged to apply them in their home environment in order to facilitate generalisation of skills. Peck (1985) states that the conclusion that the intervention was responsible for any change observed can be more confidently made where the clinical problem is of long duration and a long follow-up is used. Although the latter would ideally have been extended, the former factor was true of all participants in the current study and therefore strengthens the conclusion that changes occurred as a result of the intervention.

A further constraint of the study design was that by phase A", participants had received both four weeks treatment at the PMP and the individual session. It is therefore only possible to assess the *combined* additional effect of attending the full PMP and the individual session, and not the contribution to treatment efficacy made by each. Furthermore, it is not clear which aspects of the two combined interventions effected change in participants' sleep pattern, quality, distress and self-efficacy. It is unwise to simply assume that they have additive effects and indeed, ineffective methods may cancel out the effects of effective ones (Linton, 1994). This problem is recognised within the field of pain management (e.g. McQuay, Moore, Eccleston, Morley & Williams, 1997) and can only be rectified by studies designed to evaluate which techniques contribute to improved outcome.

**Comparison with other studies.** In the single case studies described by Morin *et al.* (1989; 1990), substantial changes in sleep parameters (e.g. an increase in sleep duration of 3.5 hours) are reported following intervention. Whilst the majority of participants in the current study made improvements in their sleep, none showed such sizable changes. Differences in treatment procedures between the two studies may explain this discrepancy in treatment outcome.

Firstly, in their studies Morin *et al.* (1989; 1990) applied sleep restriction procedures. The multi-component intervention used in the present study did not include this intervention in view of the time constraints and number of overall demands on patients during their time on the PMP. Further research would be required to investigate whether sleep restriction therapy produces superior results for patients with chronic pain.

Secondly, Morin *et al.* (1989) tapered all patients off amitriptyline and restricted their use of analgesics prior to the beginning of treatment. This is standard practice in insomnia research. It would be difficult to carry this out before the start of the PMP; medication reduction is typically commenced while patients are on the programme. This difference in practice may however have compromised outcome in the present study. Reviewers seem to have reached consensus that those patients who continue as regular users of sleep medications benefit less from treatment (Lacks & Morin, 1992; Morin *et al.*, 1994). It is hypothesized that this occurs as a result of drug users having a lower self-efficacy for falling asleep naturally, which reduces expectancy of improvement and consequently undermines treatment (Murtagh & Greenwood, 1995).



## **PART II**

**The psychological processes which determine and maintain the relationship between participants' experience of chronic pain and insomnia, and their response to treatment.**

### **5.3 Interpretation of Transcript Data**

An interpretation of Part II participants' experiences of chronic pain and insomnia is made in the following section. The relationship of each theme to previous research is discussed.

**Disruption of sleep by pain.** All participants described disruption of their sleep due to pain. They explained that pain interfered with their ability to initiate sleep, woke them during the night and affected the depth and quality of their sleep. For some participants this was exacerbated when lying in certain positions.

Comfort at night, and freedom from intrusions, are widely recognised to be significant (although not essential) factors contributing to satisfactory sleep (Espie, 1991). It seems that participants' pain prevented them from achieving the important requirements of comfort and freedom from intrusions in order to sleep.

This finding is consistent with the proposals of Mitler *et al.* (1991) that the symptoms of a medical disorder (in this instance, pain) may be sufficiently disturbing to arouse the patient and prevent the continuous relaxation necessary for sleep, and that certain medical conditions may be exacerbated by sleeping in the recumbent position. Similarly, it is consistent with the findings of several studies that insomnia is correlated with the severity of pain (e.g. Affleck *et al.*, 1996; Wilson *et al.*, 1998).

**Complaints of arousal preventing sleep.** Some participants described marked cognitive arousal at night which further prevented them from relaxing and falling asleep. Others described emotional arousal, with frustration and irritation at their inability to sleep being most frequently reported.

An accumulated body of evidence demonstrates the deleterious effect that cognitive activity can have on sleep (e.g. Gross & Borkovec, 1982), and it is typically recognised to be a symptom of anxiety or worry at night (Espie *et al.*, 1989; Watts *et al.*, 1994). Like some individuals with primary insomnia, it appears that some participants in the present study were having difficulties in sleeping due to an inability to “switch off” or as a result of racing thoughts “your brain box is going all over the place”.

The majority of participants in the current study, however, described their emotional response to poor sleep in terms of irritation and frustration rather than anxiety. It appears that perhaps unlike individuals with primary insomnia, participants were clearly able to identify the factor preventing them from sleeping and this became the focus for their annoyance. P10, for example, described herself as “very annoyed” at her inability to sleep, explaining that “even though you want to, because of the pain you cannot sleep”.

The link between pain, emotional arousal and poor sleep is reflected on by P11 who stated

*“I try and get off to sleep. I get at the most an hour, then I’m awake, and I’m irritated all the time ... and the more irritated I get the more thoughts are going through your mind, and you know the pain’s not getting better more than anything ... then the most I get is two or three hours kip”.*

Participants' experiences in this regard are consistent with the theory of a vicious cycle of poor sleep resulting in affective disturbance, which increases pain, and thereby further disturbs sleep (Moldofsky *et al.*, 1975).

**The dilemma of using or not using external means to aid sleep.** Some participants described having found sedating medication helpful, particularly as a means of initiating sleep. Some, however, used external aids to help them sleep with reservations, and others were adamant that they disliked the sedative effects of the medication (P3: "like walking round with a sheep in my earhole"), and preferred to tolerate the pain and their difficulties with sleeping.

The literature on insomnia describes the problems and limitations of benzodiazepines as a treatment for chronic insomnia (Espie, 1991; Morin *et al.*, 1989). The potential benefits and side effects of sedative antidepressants appears to have received comparatively little attention, however. In neither instance do patients' perceptions of the advantages and disadvantages of pharmacological therapy seem to have been explored. It is not clear whether these are mediated by patients' different physiological responses to the medication, their beliefs about the pharmacological treatment, or an interaction between the two. Given the accounts of participants in the current study, this would seem to be an important area for future investigation.

**Failure of problem solving attempts.** Participants described the extent of their attempts to alleviate their difficulties in sleeping and some reported that nothing they tried was helpful. The pattern and variability of their sleep was described as illogical and confusing, and they described themselves as resigned to coping with the disturbance as it was.



Attribution theory describes how in the face of threat, individuals seek reasons for the threat in an endeavour to understand, predict and control it (Kelley, 1967). Participants in the current study had been active in their attempts to understand their situation and try means of resolving it. For example, several described getting up late in the mornings, either to nap, or to prevent boredom from having little else to do during the day, and several used stimulating activities as means of alleviating boredom and distracting themselves from pain at night. Behavioural theories of sleep would suggest that these coping strategies would be more likely to compound individuals' difficulties with sleeping than alleviate them, however (Bootzin 1972; Spielman *et al.*, 1987).

Where individuals are unable to explain experiences, and do not feel they have means to control their environment, then this may lead to learned helplessness (Abramson, Seligman & Teasdale, 1979). Where participants were unable to identify reasons for their sleep pattern, and felt that there was nothing they could do to alleviate their problems in sleeping, then this may have been linked to greater distress associated with sleep. This was not examined in the current study but the importance of patient beliefs as both a contributory factor in insomnia, and determinant of the outcome of treatment, have been highlighted in research on primary insomnia (Sloan *et al.*, 1993; Chambers, 1992). This area has not, however, been examined in the literature on chronic pain and insomnia.

**Lack of pre-pain satisfying sleep.** Participants described a longing to return pre-pain satisfying sleep. They used comparisons with other people and themselves before the onset of their pain, and described the negative effects of their poor sleep on both themselves and their families, to emphasise their dissatisfaction with their present sleep.

The deleterious effect that primary insomnia can have on both the individual concerned, and their families, has been clearly described by researchers (Horne, 1988; Lacks & Morin, 1992), and its significance as a problem in chronic pain has been emphasised (Wilson *et al.*, 1998). The participants in Osborn & Smith's (1998) IPA into the experience of lower back pain, used comparisons with themselves and others to describe and evaluate their experience of having chronic pain. Osborn & Smith (1998) report that "their pain had imposed change and denied them the opportunity to be who they once were and wished still to be"(pp. 76). Participants' sadness over their lack of satisfying sleep may have been part of a wider theme concerning multiple losses and changes in their identity as a result of having chronic pain.

#### **5.4 Interpretation of Part 1 Participants Post-treatment Comments**

**Success of Problem Solving Attempts.** In contrast to their confusion and helplessness prior to treatment, most participants described an enhanced understanding of factors influencing their sleep, and strategies they could use to ameliorate difficulties. A minority, however, continued to report that nothing helped.

**Redefinition of the Problem.** Some participants described how even though they continued to experience disturbance of their sleep, it no longer caused them distress or concern.

Hauri (1989) argues that in the cognitive-behavioural treatment of insomnia, the patient's redefinition of the sleeping problem as a "condition of living", or a handicap that needs to be overcome, is a crucial first step in successful therapy. He goes on to discuss the importance of self-monitoring in helping patients to recognise factors exacerbating poor sleep. These goals of therapy are summarized by Bootzin (in Sloan *et al.*, 1993) who states that the aim of

treatment is “to move the person from a place where he views himself as the victim of a problem that is out of his control to a position where he feels that things are not as bad as he thought, and that he has the skills to help deal with a poor night’s sleep when it occurs” (pp. 27).

It would seem possible that individuals who change their view of their sleep problem achieve changes in sleep related distress and self-efficacy, and consequently the severity of their sleep disturbance. Such an outcome would be consistent with theories highlighting the importance of patients’ cognitions in the aetiology and maintenance of insomnia (Chambers, 1992). The relevance of self-efficacy beliefs to insomnia has been long recognised (Killen & Coates, 1979) and successful behavioural treatment of insomnia has been associated with reports of increased mastery (Espie & Lindsay, 1985).

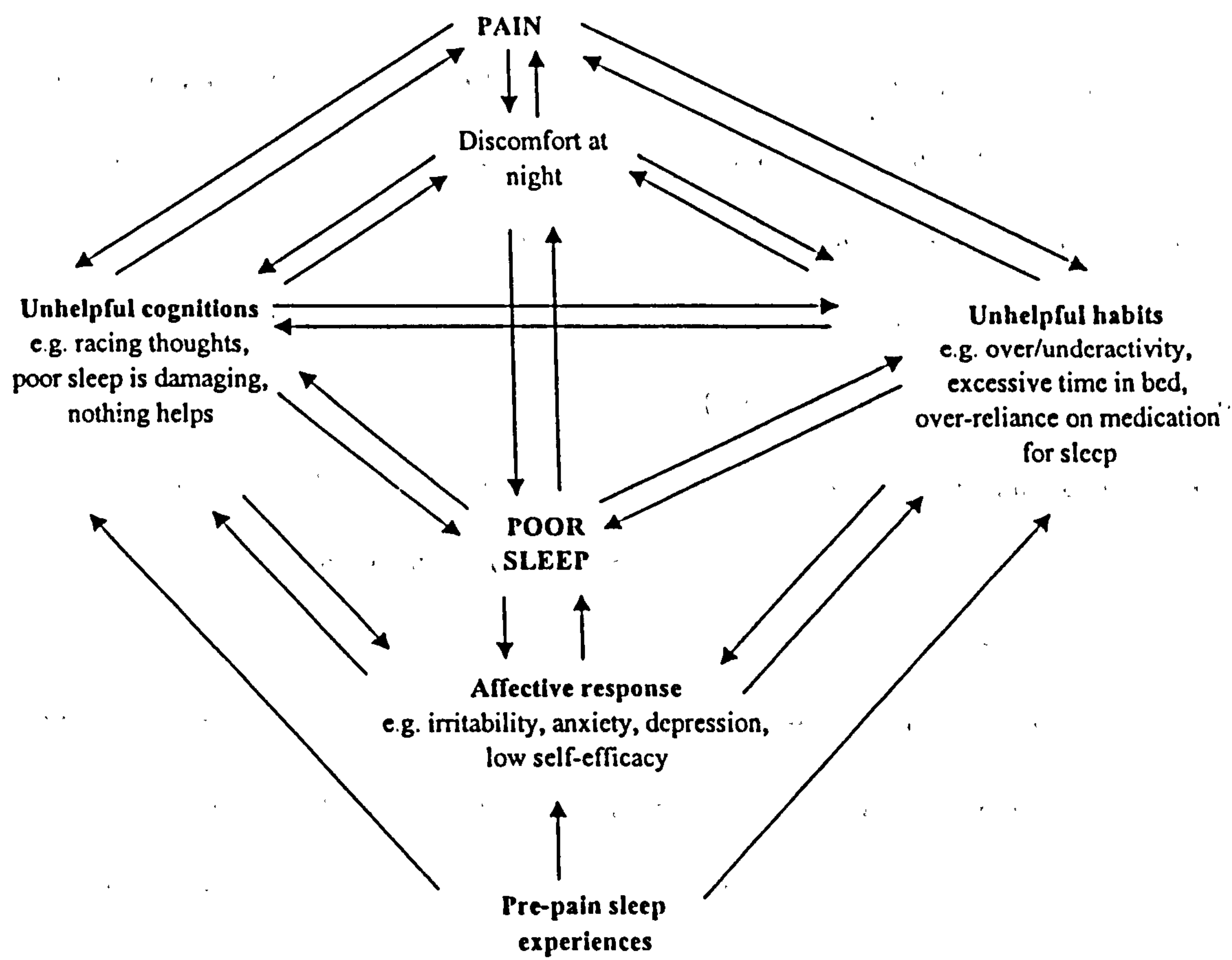
### **5.5 A Multi-Dimensional Model of Insomnia Associated with Chronic Pain**

The results of the analysis of both the transcripts and post-treatment comments would seem to suggest the importance of patient beliefs and attitudes concerning the aetiology and management of their sleep problem, and underscore the significance of a range of factors, which may interact with each other, in determining poor sleep in this population. Previous explanations of insomnia in people with chronic pain have separately considered the role of medical illness and treatments (Mitler *et al*, 1991), sleep deprivation and affective disturbance



(Moldofsky *et al.*,1975), and behavioural factors (Morin *et al.*, 1989). The role of patient cognitions has not, however, been examined. A multi-dimensional model of insomnia associated with chronic pain is therefore proposed which has arisen from both the interpretation of the themes described above, and consideration of extant theoretical understanding of both primary insomnia and insomnia associated with chronic pain. Both cognitive and behavioural responses to poor sleep are considered, and the reciprocal relationship between pain and sleep, the effect of chronic pain on patients' beliefs and habits, and the potential role of pre-pain sleep experiences are acknowledged. See Figure 6.

Figure 6. A multi-dimensional model of insomnia associated with chronic pain



## **5.6 Critical Review**

The qualitative method of analysis allowed for a detailed inspection of participants' views of their pain associated sleep problem and changes as a result of intervention. As a qualitative approach which focusses on patient beliefs (cf. discourse analysis, for example), IPA, informed both the individualised cognitive-behavioural intervention and the single case analysis of the outcome of treatment. The approach was thus seen as complimentary to the methods used in part I of this study. Smith (1996b), however, argues that the strength of IPA is in enabling a detailed analysis of how a person is thinking about, and coping with, complex health-related questions, and that to employ it in conjunction with quantitative research, whilst helpful in illuminating the processes explored at a macro level by the quantitative analysis, is a weak use of the approach.

A more detailed exploration of participants' beliefs could have been undertaken in the current study by taking the analysis of responses back to participants to enable them to both check and comment further on the interpretation. This would have been particularly interesting to carry out at the post-treatment stage because it would have allowed a more detailed exploration of participant accounts at this juncture and perhaps further illuminated changes in perceptions following treatment. It is not clear from the present analysis what it means when themes fail to re-emerge after treatment. It would also have been of interest to explore further the meanings of a reduction in sleep-related medication with those participants who made changes in this domain and those who did not. Practical constraints prevented this from being carried out but the procedure would have also had the advantage of allowing the validity of the interpretation to be assessed by another means (member validation).

A further method of checking the validity of the analysis, which is also said to strengthen the interpretation of the account, and facilitate the acquisition of a full and rich account of the phenomenon being explored, is to use a number of different sources to gain information on the topic of interest. This procedure is termed 'triangulation' and is described by Smith (1996a) as "a way of capturing the multiple 'voices', and therefore truths that exist in relation to any phenomena". In the current study this might have involved interviews with participants' partners and/or programme staff regarding their understanding of the problem, or perhaps asking participants to keep a record of their thoughts and feelings in relation to their sleep in the sleep diaries they were using. Again, practical considerations prohibited the extension of the study in this way.

## **PARTS I and II**

### **5.7 Clinical Implications**

**Contribution to Clinical Psychology.** To the author's knowledge, this is the first qualitative analysis of patients' experiences of insomnia associated with chronic pain and its treatment, and the first single case series to be conducted on the use of a individualised cognitive-behavioural intervention for insomnia secondary to chronic pain carried out within the context of a PMP. A multi-dimensional model of insomnia in this population is proposed which unlike previous explanations, includes the consideration of patient beliefs and attitudes in relation to their sleep. Assessment of participants' sleep underscores the significance of the problem highlighted in previous studies (Wilson *et al.*, 1998) but there is reason to be at least encouraged regarding the efficacy of a PMP and tailored cognitive-behavioural intervention in improving



patients' sleep. Further research would, however, need to be carried out in this area before the approach could be confidently applied to all patients with chronic pain, particularly those in other settings.

**Implications for Clinical Practice.** The results of this study highlight the need for the consideration of sleep on all PMPs. It is an important aspect of quality of life that has been significantly impaired for the majority of patients with chronic pain, and can cause much distress, yet is rarely considered to be sufficiently important to be included in PMP outcome measures (Williams, 1995). Awareness of patients' problems in sleeping, and the possible subsequent effects this might have on pain intensity, distress and concentration during the residential phases of a PMP would also seem important: results of the current study indicated that the majority of sleep diary completers experienced a clinically significant deterioration in at least one parameter of sleep during the first two weeks of their stay.

The importance of a multi-dimensional approach to both assessment and intervention, which includes consideration of patients' thoughts, beliefs and attitudes concerning their sleep, is emphasised from the results of this study. It would not seem sufficient to focus on just one factor thought to be causing or maintaining insomnia. This is where the multi-disciplinary team approach is particularly important (Flor *et al.*, 1992). Where individuals are engaging in unhelpful habits concerning their sleep then the meaning of the behaviour to that individual might be usefully explored. For example, one of the reasons participants in the current study gave for prolonging their time in bed in the mornings was their boredom during the day. Occupational Therapy intervention to plan meaningful daytime activities would thus be important.

It appears that the sedative antidepressants prescribed to patients with chronic pain to help them sleep, may for some individuals, result in more problems than benefits, and for those individuals continuing to take them, reservations are reported. If patients wish to reduce their use of sleep-related medication, or if where this is excessive, it is one of the aims of treatment, then the techniques employed in motivational enhancement therapy (Miller & Rollnick, 1991) may be relevant. The transtheoretical model of behaviour change (Prochaska & DiClemente, 1984) proposes that one of the variables responsible for an individual making changes in a behavioural pattern, is what they term 'decisional balance' (i.e. weighing up the pros and cons of behavioural change). Motivational enhancement therapy advocates helping patients to explore their reservations in an explicit manner in order to facilitate behavioural change.

Finally, the results of the current study would seem encouraging concerning the efficacy of a PMP and individualised intervention for reducing insomnia in chronic pain. More investigation is required, however, before the approach can be confidently generalised to all patients with chronic pain and its effective ingredients will need to be identified. A first step will be to raise clinicians' awareness of the extent of the problem. It is hoped that dissemination of these results to professionals working in the field of pain management will stimulate greater interest in this currently neglected source of patient distress and disability, and hence more research into effective intervention.

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## APPENDICES

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## APPENDIX 1

### DESCRIPTION OF PMP TREATMENT COMPONENTS

The main components of both the two and four week programmes, using cognitive-behavioural principles throughout, were as follows:

**Exercise and stretch** to improve fitness and flexibility, to build muscle strength, and to remedy specific postural problems. Exercises began at a baseline around 80 per cent of patients' current performance, and increased gradually on a quota system; patients recorded and were reinforced with contingent praise (or reinforced themselves) for achievements of quotas.

**Goal setting** on long- and short term goals identified by patients, and covering work, leisure and social pursuits, and domestic duties. Short-term goals usually included increasing sitting, standing, and walking tolerances. Baselines and rate of increase were set as for exercises.

**Pacing of activities** (i.e. a regular schedule of activities and breaks, with activities increasing on the quota system described above) was taught, to counteract patients' tendencies to strain beyond their current physical capacity, and/or take prolonged rest. A timer with an alarm was carried by patients to remind them to change position or activity (Gil et al., 1988).

**Education sessions** (conducted by all team members) covered concepts of chronic and acute pain, medical/surgical treatments, disuse, healthy function, medication, and sleep and sleep problems. All teaching was interactive, using patients' own experience.

**Cognitive and behavioural sessions** on problem solving, changing maladaptive behaviours, maintaining those changes, and the use of cognitive techniques to identify unrealistic and unhelpful thoughts and beliefs, and to change them. The use of cues and self-reinforcement was encouraged, as was self-monitoring and thought recording. All staff systematically reinforced patients' achievements with praise (fading this towards the end of patients' stay), and avoided reinforcing pain behaviours.

**Drug reduction** applied to all pain-related drugs, including tranquillisers, sedatives, hypnotics and antidepressants, which had not proved helpful in improving patients' pain or function. Current drug intake was reviewed with the patient, and the rate of reduction of each substance jointly agreed; the aim was usually nil by discharge, with more gradual reduction of large doses of benzodiazepines. The patient chose to reduce either by cocktail (Fordyce, 1976) or by self-controlled reduction using the patient's own supply of tablets. Full details of these methods are given in Ralphs *et al.* (1994). Patients were encouraged to substitute alternative coping strategies for their usual recourse to medication.

**Relaxation** consisted of a simple technique to be used while active; patients were encouraged to practise during the day and evening, and to monitor their performance. In conjunction, use of distraction, imagery, and by contrast, dispassionate focus on the pain, were taught.

**Sleep management** consisted of sleep hygiene techniques, relaxation, and cognitive methods (Lacks, 1987; Morin et al., 1989).

**Relapse prevention** and maintenance of new behaviours and skills were promoted throughout. Patients made 'set-back plans' for dealing with crises, including revision of techniques using the patient manual, and contact with staff and fellow patients. The discharge letter to the referrer and GP included recommendations for further management and help in crises.

**Family involvement** was encouraged by inviting spouses and 'significant others' to attend at least one day of the programme, including a discussion and information giving session without their relatives present.

Largely taken from Williams *et al.*, (1996).

## **APPENDIX 2**

### **PMP INCLUSION CRITERIA**

Patients were assessed by an anaesthetist and clinical psychologist. They were included on the PMP if they fulfilled two of the following criteria:

- (i) widespread disruption in activity (except work) owing to pain
- (ii) habitual overactivity leading to increased pain
- (iii) use of excessive medication related to pain problems (regular use of analgesics and/or sedatives for more than six months without adequate relief)
- (iv) clear signs or reports of emotional distress attributed by the patient to pain
- (v) use of unnecessary aids, such as crutches or a collar, assessed during medical examination by the anaesthetist
- (vi) high levels of reported or observed pain behaviour
- (vii) work reduced, impaired or ceased owing to pain

Patients were excluded if they met one of the following criteria:

- (i) cannot use English, written or spoken
- (ii) cannot climb stairs
- (iii) current psychotic illness
- (iv) unavailable for a four week period
- (v) suitable for further physical treatment, assessed during medical examination
- (vi) pain for less than one year
- (vii) less than 18 years old
- (viii) currently using opioid analgesics prescribed as treatment for drug dependence; or not prescribed for patient.

# APPENDIX 3

## HOSPITAL RESEARCH ETHICS COMMITTEE

2 October 1998

Chairman - [REDACTED]

Administrator - [REDACTED]

Ms K Treves

Dear Ms Treves

**EC98/125      The management of insomnia on a residential pain management  
programme: ten single case analyses**  
*Ms K Treves, Dr A Williams, Dr R Dallos*

Thank you for submitting the above application. This application has been approved at the Research Ethics Committee at its meeting on 29 September 1998.

Please note that this project carries a reference number, noted above, which must be quoted in any future correspondence.

The project number and the principal investigator must be clearly stated on the consent form. If approval is given to named investigators only, these names must also be stated on the form.

In the case of research on patients, a copy of the consent form must be placed in the patient's medical records, together with a note of the date of commencement of his/her participation in the research. A label must appear on the outside cover of the records when the patient is participating in the research.

The investigators must adhere to the published Guidelines of the Committee and provide the Chairman with progress reports if requested. The research should start within 12 months of the date of approval.

Yours sincerely

[REDACTED]  
Chairman,  
Research Ethics Committee



[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

Dear

During the time you are at ~~rehab~~ we will be carrying out a small research study concerning sleep problems associated with chronic pain.

The study aims:

- ◇ to help us understand more about the factors that cause difficulties in sleeping for people with chronic pain; and
- ◇ to see whether having extra advice whilst on the programme helps improve people's sleep.

When you attend your pre-treatment appointment you will be invited to take part. The information sheet enclosed tells you more about the study. Participation in the study is entirely voluntary and if you decide not to take part, this will not affect your treatment at the Unit in any way.

I will be happy to answer any questions you may have when you attend your pre-treatment appointment. I look forward to meeting with you then.

Yours sincerely

[REDACTED]

Principal Investigator

Encl.

[REDACTED]  
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Dear

During the time you are at [REDACTED] we will be carrying out a small research study concerning sleep problems associated with chronic pain.

The study aims:

- ◊ to help us understand more about the factors that cause difficulties in sleeping for people with chronic pain; and
- [REDACTED]

[REDACTED]. The information sheet enclosed tells you more about the study. Participation in the study is entirely voluntary and if you decide not to take part, this will not affect your treatment at the Unit in any way.

I will be happy to answer any questions you may have when you attend your pre-treatment appointment. I look forward to meeting with you then.

Yours sincerely

[REDACTED]  
Principal Investigator

Encl.

[REDACTED]

**INFORMATION SHEET FOR PARTICIPATION IN RESEARCH PROJECTS & CLINICAL TRIALS****Title of Project:**

The management of insomnia on a residential pain management programme: ten single case analyses.

**Principal Investigator:**

[REDACTED] Chartered Clinical Psychologist

**Other Investigator/s**

[REDACTED]

enrolling patients:

**Ethics Committee**

Code No:

EC98 / 125

**Outline explanation:**

You are invited to take part in a study being conducted at [REDACTED] concerning sleep problems associated with chronic pain.

The study is being carried out for research purposes to help us:

- 1.) Understand more about the factors that cause difficulties in sleeping.
- 2.) To see whether having extra advice on the programme helps improve peoples' sleep.

Taking part in the study will involve:

- 1.) Completing a diary when you wake up each morning from the date of your pre-treatment to date of the one month follow-up appointment. The diary asks you to record the time you went to bed, woke up, the length of your sleep, its overall quality, if you had difficulty getting off to sleep, if you woke during the night and how upset you felt about any difficulty in sleeping.
- 2.) Discussing the sleep problem with the Principal Investigator at your pre-treatment appointment and at the end of the programme. To help her to have an accurate record of what you said, the interview will be tape recorded.
- 3.) Receiving clinical advice from the Principal Investigator about how you can best manage your problem in sleeping at an appointment during your time on the programme.

Your treatment on the pain management programme will not be affected by taking part in the study. You will just receive some extra individual advice concerning the management of your sleep problem.

All information collected in the study will be kept confidential. No one will have access to the diary or tapes other than the Principal Investigator. The taped interviews will be wiped clean once the investigator has made a record of what you said.

Participation in the study is entirely voluntary.

If you decide to take part you may withdraw from the study at any time without affecting your future care and treatment.



## INFORMATION SHEET FOR PARTICIPATION IN RESEARCH PROJECTS &amp; CLINICAL TRIALS

## Title of Project:

The management of insomnia on a residential pain management programme: ten single case analyses.

## Principal Investigator:

[REDACTED] Chartered Clinical Psychologist

## Other Investigator/s

[REDACTED]

enrolling patients:

## Ethics Committee

Code No:

EC 18 / 125

## Outline explanation:

You are invited to take part in a study being conducted at ~~WIMBORNE~~ concerning sleep problems associated with chronic pain.

The study is being carried out for research purposes to help us:

1.) Understand more about the factors that cause difficulties in sleeping.

[REDACTED]

Taking part in the study will involve:

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

2.) Discussing the sleep problem with the Principal Investigator [REDACTED]

[REDACTED]. To help her to have an accurate record of what you said, the interview will be tape recorded.

[REDACTED]  
[REDACTED]

Your treatment on the pain management programme will not be affected by taking part in the study. [REDACTED]

[REDACTED]

All information collected in the study will be kept confidential. No one will have access to the ~~diary~~ tapes other than the Principal Investigator. The taped interviews will be wiped clean once the investigator has made a record of what you said.

Participation in the study is entirely voluntary.

If you decide to take part you may withdraw from the study at any time without affecting your future care and treatment.

**TEXT BOUND  
INTO  
THE SPINE**

**CONSENT FORM FOR PARTICIPATION IN RESEARCH PROJECTS & CLINICAL TRIALS****Title of Project:**

The management of insomnia on a residential pain management programme: ten single case analyses.

**Principal Investigator:**

[redacted] Chartered Clinical Psychologist

**Other Investigator/s**

[redacted]

enrolling patients:

**Ethics Committee****Code No:**

EC98/125

**Outline explanation:**

See information sheet.

**I (name)** \_\_\_\_\_**of (address)** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

hereby consent to take part in the above investigation, the nature and purpose of which have been explained to me. Any questions I wished to ask have been answered to my satisfaction. I understand that I may withdraw from the investigation at any stage without necessarily giving a reason for doing so and that this will in no way affect the care I receive as a patient

**SIGNED (Volunteer)** \_\_\_\_\_**Date** \_\_\_\_\_**(Doctor)** \_\_\_\_\_**Date** \_\_\_\_\_**(Witness, where appropriate)** \_\_\_\_\_**Date** \_\_\_\_\_**3 copies required: one for researcher, one for patient/volunteer, one for patient's notes**



## PITTSBURGH SLEEP QUALITY INDEX

The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month.

Please answer all questions.

- 1 During the past month, when have you usually gone to bed at night?

Usual bed time \_\_\_\_\_

- 2 During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

Number of minutes \_\_\_\_\_

- 3 During the past month, when have you usually got up in the morning?

Usual getting up time \_\_\_\_\_

- 4 During the past month, how many hours of actual sleep did you get each night? (This may be different from the number of hours in bed.)

Hours of sleep per night \_\_\_\_\_

For each of the remaining questions, circle or tick the one best response. Please answer all questions.

- 5 During the past month, how often have you had trouble sleeping because you . . .

- a) Cannot get to sleep within 30 minutes.

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
------------------------------	--------------------------	-------------------------	-------------------------------

- b) Wake up in the middle of the night or early morning and cannot get back to sleep.

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
------------------------------	--------------------------	-------------------------	-------------------------------

- c) Have to get up to use the bathroom.

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
------------------------------	--------------------------	-------------------------	-------------------------------

- d) Cannot breathe comfortably.

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
------------------------------	--------------------------	-------------------------	-------------------------------

**TEXT BOUND  
INTO  
THE SPINE**

**BEST COPY  
AVAILABLE**

**Variable print  
quality**



e) Cough or snore loudly.

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
------------------------------	--------------------------	-------------------------	-------------------------------

f) Feel too cold.

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
------------------------------	--------------------------	-------------------------	-------------------------------

g) Feel too hot.

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
------------------------------	--------------------------	-------------------------	-------------------------------

h) Had bad dreams.

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
------------------------------	--------------------------	-------------------------	-------------------------------

i) Have pain.

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
------------------------------	--------------------------	-------------------------	-------------------------------

j) Other reason(s) (Please describe) . . . . .

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
------------------------------	--------------------------	-------------------------	-------------------------------

5 During the past month, how would you rate your sleep quality overall?

Very good	[ ]	Fairly bad	[ ]
Fairly good	[ ]	Very bad	[ ]

7 During the past month, how often have you taken medicine (prescribed or 'over the counter') to help you sleep?

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
------------------------------	--------------------------	-------------------------	-------------------------------

3 During the past month, how often have you had trouble staying awake while driving, eating meals, or engaged in social activity?

Not during the past month	Less than once a week	Once or twice a week	Three or more times a week
------------------------------	--------------------------	-------------------------	-------------------------------

9 During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all	[ ]	Somewhat of a problem	[ ]
Only a very slight problem	[ ]	A very big problem	[ ]

# APPENDIX 9

## Sleep Study

On a scale of 0 to 5, where 0 is low and 5 is high,

- (1) How much distress would you say your difficulty in sleeping has caused you over the past month?

---

- (2) How confident would you say you have been in your ability to cope with your difficulty in sleeping?

---

Thank you

## **APPENDIX 12**

### **INTERVIEW SCHEDULE**

- (1) Just tell me about your sleep.
- (2) What do you do when you are unable to sleep?
- (3) How are you feeling in the night when you are unable to sleep?
- (4) What is going through your mind - what kind of things are you saying to yourself?
- (5) Does it (your difficulty with sleeping) affect other people as well as you?
- (6) How are you when you wake up in the morning after your night's sleep?

### **Post-treatment assessment**

- (1) How is your sleep?
- (2) If improvements were reported, 'What do you think is helping?'
- (3) and if a deterioration was described, 'Why do you think that is?'.



## APPENDIX 14

### Sample intervention letter

Dear XXXXX,

First of all thank you very much for your help in completing the diaries of your sleep. These will not only help us to monitor the pattern of your sleep, but will also contribute to the research I am doing on chronic pain and sleep. From talking to you, and looking at your diaries, the following may be useful points:

1. The first important point we discussed is your use of your computer late at night. There are three 'dangers' with this: (i) Using the computer is an arousing, rather than calming activity, and hence you find it is still all going through your mind when you get to bed, which keeps you awake. (ii) It may also have had the effect of getting your body into a habit of being stimulated at night, rather than rested, so you have learned to be awake at this time. (iii) Because you tend to oversit as well, it is an activity that may well be increasing your pain late at night, and thus it is harder to get to sleep.

It would be best to avoid using the computer for at least one hour before you go to sleep, and preferably longer. I know this is something for you to weigh up as to whether you want to continue with the studies anyway; it would be a good idea to talk to our Specialist Work OT, XXXX, about this.

2. Related to the above, is having a relaxing routine to help you settle at night, and to let your body know that it is time to sleep. It is great to hear that you are finding the stretch routine helpful to reduce the cramps you get at night, so it is probably a good idea to do a few gentle stretches before you go to bed. Other strategies you may want to try include some of the relaxation and breathing techniques. The important thing is that you are helping your body wind down, and giving it cues (reminders) that it is time to fall asleep.

3. With regards to the timing, in order to help you lengthen the amount of sleep and rest you get at night, it will be important to have a regular time to wake and get up each day. It sounds as if this is imposed upon you by your children! The other important aspect is to perhaps try going to bed a little earlier each night. It will be important to take a gradual approach with this, so to perhaps go to bed just a quarter of an hour earlier than your usual average. Try it for a week, and then perhaps go a quarter of an hour earlier still, so you are gradually introducing your body to an earlier bed time.

4. Finally, it sounds as if you are aware of some of the unhelpful thoughts you have when you cannot sleep at night. If these lead to feelings of frustration or worry, then they are likely to be intruding further on your sleep. It is thus perhaps a good idea to have some challenges - i.e. helpful thoughts - ready prepared. It would certainly make a good example for a thoughts form...

I hope this makes some sense XXXXX, check with me or XXXXX if it doesn't. As we discussed, it can take a while to make changes in sleep, since the habits have often established over a long period of time. You will also need to work hard at implementing these changes and it isn't uncommon for people to find their sleep a bit worse in the short-term, before they begin to reap the benefits.

I'll look forward to hearing how you get on and to your next set of diaries.

Yours sincerely,

XXXXXXX  
Investigator

## APPENDIX 15

P And I know I'm dreaming and I've just woken up.

I Right

P No nightmares or nothing. Nothing bad, no.

I Not nightmares.

P No dreams

I Just dreaming and you're waking up between two and three, around that time. Just after midnight. After an hour or so.

P Yes

I And would it take you a while to get off to sleep once you've woken?

P A few minutes, no. But I know that the medications are taking effect as well.

I Right. So the amitriptyline..

P Yes the amitriptyline, that makes a difference after one o' clock, between twelve and one. It has its effect. I get heavier and heavier.

I So you can feel the..

P I can feel the effect.

I Well shall we finish there? Have we missed anything out?

P I don't think so.

### INTERVIEW 3.

I OK if you want to tell me how the pain actually <sup>a</sup>ffects your sleep.

P I have trouble getting to sleep. I can't get into a comfortable position to get to sleep.

I Right.

P And that can take a couple of hours just to get from going to bed to falling asleep.

I Mm hmm

P Can take a couple of hours.

I Right

P I can wake up anywhere between two and ten times a night.

benefit of  
amitriptyline

Comfortable  
position

Latency

WAKES +T

INTRUSION  
ON  
SLEEP

## APPENDIX 15

I Right.

P That makes me slightly less tolerant of every body else.

I Right. Is that when you've had a bad night's sleep?

P Yeah well when I've had .. I'm not too bad with just a day's loss of sleep it's when it starts getting consecutive three or four days in a row that's when I start getting unpleasant to live with I suppose is the best way of putting it.

I Right

P And I say it can go on ..about the longest I've had now is just over a week and in that week we worked it out I'd had about eight hours sleep.

I Right, over a week?

P Eight hours broken sleep over the week. So that was when I decided to take the amitriptyline and go to sleep full stop.

I So do you do that often?

P No. I don't like the effects of amitriptyline. It tends to fog my head. I just don't know so - and I don't like that effect.

I Yeah

P I spent about eighteen months with my brain wrapped in cotton wool and I had enough of it. I want ..I'd rather put up with a bit more pain.

I Uh huh

P And know that the pain is affecting me because I can -I feel it more but I'm able to hold conversations and generally get on with my life as much as I'm capable of..

I Mm Mm

P I was on amitriptyline and dihydrocodeine..

I Mm

P And I just didn't know which way was up.

I Right

P Now I lose my sleep over it but at least I..

I At least you're clear..

P During the day I can have a conversation with somebody and not deny the next day that I'd even seen them which has happened.

I Right.

LACK  
OF  
SATISFACTORY  
SLEEP

→ irritability due to  
→ poor sleep

effects on others

- So bad I took the  
amitriptyline

-ve effects of  
amitriptyline:

The benefits are  
outweighed by  
the disadvs

sedation

DILEMMA  
OF USING  
EXT. AID  
FOR SLEEP



## APPENDIX 15

P I've got more time for the kids. It's more painful but I mean I've got a four and a two year old - he's nearly three so ..... it's a double edged sword being in pain all the time. I'm there all the time with them. I see the development most dad's miss out on. But unfortunately I just can't do as much as I'd like to.

effects on family  
might be a bit  
for them

I Yes. But you don't want to miss out on them by the sound of it, being with the amitryptiline, even though it helps your sleep, you don't want the side effects of that.

P It was alright for me but it was very isolating.

-ve effects of  
amitryptiline

I Mm

P I wasn't in contact with my family.

I Mm

P So I don't. I usually leave the amitryptiline alone until it's got, nowadays it's got to three or four days, and then I think that's enough.

I Right

P I've got to get some sleep, I'm getting too miserable - antisocial, whatever. Go to sleep for a day, a day and a half,

- ves

I Mm Hm

P And if I can knock myself out well enough

I Mmm

P So I do actually get some decent sleep.

benefits of amitryptiline

I Mm

P I tend to wake up in not so much pain as well.

→ sleep relieves  
pain

I Right.

P It's not major, but it's noticeable. I don't know any other way to explain it

I yeah

P by knocking myself out for 24-36 hours I can get up and I know that I'm still in pain and it's difficult getting around but it's not as painful..

I Right. That's interesting isn't it?

P So I don't know-something relaxes, something switches off, it all gets easier so... but as I say I know that after that, if I knock myself out for the day, for the next couple of days I'm going to be walking around with a sheep in my carhole, so I don't, I try to leave them alone.

-ve effects of  
amitryptiline

DRAMA  
OF USE  
OF DRUGS

LACK OF  
SATISFYING  
SLEEP

## APPENDIX 15

I So you try to do without them. Does anything else help your sleep other than the amitriptyline? Is there anything else that you do to try and help it?

P Not really. I say I don't believe in potions and pills for knocking yourself out.

I Mm

P But I believe that occasionally I've got to so I do. But I don't ... someone gave me a relaxation tape. It helps put me in the right frame of mind to get to sleep, but not often.

I Right

P I don't have any problem with the actual frame of mind. I want to go to sleep -, it's a good time to go to sleep, as everybody does, everybody gets to that.

I mm

P I have the problem of converting thought to action. My body won't let me go to sleep. My head says 'shut down time', go to sleep, and my body says you're having a laugh!

I Right

P 'You've got no chance.' So..

I So the thought is there but ..

P So the relaxation tapes just tend to end up annoying me in the long run. They achieve their aim, they get me nice and relaxed, and I want to get to sleep, but I can't.

I Right. So you're kind of ready for sleep but its still not coming..

P Yeah. So in the long term, they're 'a waste of bloody space' (shouts). No they're not, they're good for what they are but..

I It's not the whole answer..

P Yeah

I And what do you do in the night when you wake up, and you can't get bak to sleep, what would you be doing at those times?

P Watching television, playing on the computer, reading.

I mm Hm

P The only thing I don't do is anything too physical. As long as its stationary and visual. I'm very much a visually oriented person. I can't sit down and listen to music, I'd rather watch the video of it.

*role of cognition*

*I want to go to sleep - no problem with my mind*

*pain (body?) stops sleep*

*frustration*

*Coping strategies? stimulating*

*INTRUSION OF PAIN*

*AROUSAL?*

## APPENDIX 15

I Right. Yep

P I like music but I can't just sit and listen to a radio.

I Mm And how long might you be doing that for then before you go back to bed again.

P It can be all night. I've most continuous I've been awake is 76 hours, without any sleep at all

I Without any sleep..

P Yep. And I'd say I spent 90 per cent of that on my back, watching television, playing the computer or reading a book.

I Yes

P The other 10 per cent was to struggle to the loo.

I Right. Yeah.

P And it goes from that right the way through to..before I started.. last eight years. Eight years ago I was sleeping four and a half hours a night.

I Right.

P That was it. That was all I had. That was all I needed. That was all I wanted.

I Right.

P Working as a plasterer..

I Had you got your pain then or not?

P Yeah

(Goes on to talk about general limitations as a result of the pain.)

### INTERVIEW 4.

I So basically if you can just tell me the kind of ways in which your pain affects your sleep.

P Right um. Usually what I do is, if its hurting I delay going to bed for as long as possible. Becuse I know if I go to bed at twelve o' clock, I lay there for two or three hours, getting more irritated, before I eventually doze off. Um if I'm really tired it's not too bad, I can just go to bed at a reasonable time, by about eleven, and I'll be gone fairly quickly..

I Right

Started = the pain ↑

> Contrast with previous good sleep

→ attempt to cope by delaying going to bed

frustration at not sleeping

LOSS /  
LACK OF  
SATISFYING  
SLEEP



## APPENDIX 16

### Research Diary

**27<sup>th</sup> September 1998.**

This is the first entry to this record of the research process yet I guess my thoughts and plans began some months ago. Or maybe they didn't - as with my diploma research it took me a long time to finally decide on an area to investigate. Is it possible that it wasn't until I came back from Peru in July that I finally took up XXXXX's suggestion to look at insomnia in chronic pain? Yes I think that is true - I'd just been requesting articles before I went away.

Wednesday down at Salomons felt quite profitable. It was good to talk to XXXX about my plans (although I am finding that no-one understands exactly what I am doing in terms of design other than me - either because it is completely off the wall or it is just that I am explaining it to people badly - I hope it is the latter!). It was also reassuring to know that my plan to do the final three months of the course in Venezuela will be possible, and that the viva might consequently be re-scheduled for when I am back in May. It all felt quite orderly and possible as I explained it to XXX, but I shouldn't hold my breath I know; there will doubtlessly be hidden complications to writing up in a developing country which may outweigh the luxury of having the time off to work on it undisturbed!

**21<sup>st</sup> October 1998.**

XXXXX suggested I do include a global measure of sleep in the design. He also pointed out to me that 'I'd lost the plot somewhat' in my attempt to undertake a multiple case design across participants because everyone was receiving the intervention at the same time (whereas they're all meant to get it at different times). He suggested giving the individual intervention at different time points with all participants being told we wouldn't expect change until a certain point anyway (in order to control for expectancy). However with all the up and downs patients have on the programme I wasn't too sure about whether the measure would be sensitive enough to pick up any changes.

I pondered over it all today before seeing XXX but did consider that now we have two split programmes on the cards, whether some sort of ABAB design might be possible. After XXXX had pointed out that I was maybe using the wrong design to answer the questions I had (ie Does the PMP improve sleep? Does the PMP + me improve sleep more?), and I had a slight panic that I was going to have to go back to a group design again (and re-submit to ethics), he suggested an ABAB style design after I had talked about my interest in each individual's unique sleep problem. This seems a lot neater to me but I'm still unsure of whether the diary measures will be sensitive enough.

**28<sup>th</sup> October 1998.**

First participant today! It was all a bit muddly with the consent forms etc but it seemed to go OK. He made a good participant with a clear account of his sleep problem. Two were unsuitable. Two more are coming on Thursday so I'll see if I can get them. The rest won't really give me a long enough baseline (less than one week) so I guess I'll have to include some from the December intake. That's all very well but their follow-up will be mid Feb when I was planning to be in Venezuela.... Hmmm

**15<sup>th</sup> December.**

Well its happening and people are reporting changes in their sleep! Thank God we've got happy groups in at the moment... There are three currently in the study in week 4, with one reporting great benefits, but he's the one who left his baseline diary at a service station - typical! I also have five in week two; it's a bit tougher keeping tabs on them but I think they're all OK...

XXXXX seems quite animated about it all, especially the tape recorded interviews. The tricky bit will be getting those transcribed, but there's some lovely data on there, especially from the two weekers. It's amazing the quality of material you get when you record what patients actually say. I guess you only remember a fairly low proportion clinically.

I'm surprised that patients don't tend to talk about their anxieties about not sleeping, which has always been my focus in cognitive sessions with them. They talk far more about their frustration and irritability at not sleeping. No doubt this inhibits sleep onset in a similar way, but has different implications for the focus in therapy. The biggest theme however seems to be their feeling of a lack of control over sleep. In some ways I guess this is a fairly universal clinical concept but it is interesting to see how frequently it is commented on. Where participants do find means of coping, their strategies are often maladaptive - such as delaying going to bed until really late, or getting up and working on the computer in the middle of the night. These are fairly well recognised problems in insomnia research but it is interesting to see the cognitions that drives them.

**18th February.**

Time rolls on and there is still no sign of my precious shipment containing my computer, research papers and several sleep diaries. Information concerning its whereabouts seems to change each time XXXX rings. I guess the worst that can happen is that it will arrive so late that I will have to defer to September, more likely I'm just going to have a bit of a mad rush... There are eight and a half weeks to go. In some ways that sounds like a lot but I know the data analysis will be time consuming, and that the Introduction will take a long time to write. Similarly I am anxious about the remaining data coming from XXXX - will it get lost in the post?; are there missing diaries?

I guess the good thing is that I've done a fair amount of what I can over the past two and a half weeks, I've taught myself to use spread sheets, and hence have an idea of how to present the single case research. Mind you, I'm not convinced that the data is going to show much overall - it just looks a higgledy piggedly mass of points at the moment! I just feel like I'm biding time when what I want to do is get going. At least it's interesting to work on.

## APPENDIX 17

### Part I participants: Mean (SD) baseline sleep diary (DSD) scores and raw pre-treatment sleep measures.

Measure	Participants								M (SD)	Other Studies
	P1	P2	P3	P4	P5	P6	P7	P8		
DSD: Sleep Duration (hrs)	6.23 (0.61)	6.72 (0.62)	/	4.5 (1.87)	5.79 (1.52)	6.85 (1.17)	/	6.72 (1.46)	6.08 (1.45)	5.24 + (1.60)
DSD: Sleep Latency (0-3)	1.36 (0.81)	0.25 (0.46)	/	0.55 (0.82)	1.83 (0.84)	2.58 (1.17)	/	0 (0)	0.85 (0.95)	1.92 + (0.88)
DSD:Awake- nings (0-4)	2.36 (0.81)	1.38 (0.52)	/	0.73 (0.47)	0.92 (1.17)	1.92 (0.74)	/	0.78 (0.44)	1.34 (0.96)	1.78 + (0.55)
DSD: Sleep Quality (0-5)	1.64 (1.03)	2.56 (0.53)	/	2.82 (1.83)	2.58 (1.17)	2.5 (0.71)	/	2.67 (0.71)	2.45 (1.14)	2.71 + (1.09)
PSQI (raw scores: 0-21)	16	13	13	12	15	17	16	8	13.75 (2.92)	13.25# (3.40)
DNRS (raw scores: 0-5)	3	/	2	4	/	/	4	0	2.6 (1.5)	/
SENRS (raw scores: 0-5)	4	/	4	4	/	/	5	3	4 (0.63)	/

+ 46 in-patients with chronic pain (Haythornthwaite *et al.*, 1991)

# 40 patients with chronic pain treated at a rehabilitation centre (Wilson *et al.*, 1998)

**Note.**

DSD Sleep Duration: hours slept (to the closest half hour)

DSD Sleep Latency: 0=0-30 minutes; 3=90+ minutes to fall asleep at night

DSD Awakenings: 0=0 times; 4=6+ times awakened during the night where it was difficult to return to sleep

DSD Sleep Quality: 0=extremely poor; 5=extremely good quality of sleep

PSQI: 0=low score; 21=high score for sleep disturbance

DNRS: 0=low; 5=high level of distress caused by difficulty in sleeping

SENRS: 0=low; 5=high level of confidence in ability to cope with difficulty in sleeping

## APPENDIX 18

### Part I participants: Mean pre-treatment PMP outcome measures.

Measure	Participants								M (SD)	Other sample
	P1	P2	P3	P4	P5	P6	P7	P8		
Anxiety HADS (0-21)	11	10	7	11	5	11	6	2	7.88 (3.4)	11.5 + (4.4)
Depression HADS (0-21)	12	6	12	10	4	4	4	2	6.75 (3.99)	9.30 + (3.6)
Self Efficacy PSEQ (0-60)	24	35	21	24	14	27	35	27	25.88 (6.98)	24.9 + (11.5)
Catastrophising CSQ (0-36)	8	5	18	13	3	11	14	5	9.63 (5.24)	17.4 + (8.1)

Note.

High PSEQ scores indicate greater self efficacy

+ Population of 747 patients who have previously attended the PMP



CHALLENGING UNHELPFUL THOUGHTS

Name ..... Date.....

To complete the first three boxes on this form, follow the procedure you used for your previous thoughts and feelings form. Then, to complete the box headed Other More Realistic and Helpful Thoughts, consider how you could challenge what you wrote in the Initial Thoughts box. Ask yourself: (a) was that a fair judgement or statement?, (b) are there other things I could take into account? and (c) what is the evidence for thinking this way? Write down the answers to these questions and anything else that helps you put things into perspective. Next, write down how you feel after having considered your challenges. This need only be a word or two, such as 'calmer' or 'less upset'. Finally, write in the What Did You Do Next? box what (if anything) you did as a result of challenging your Initial Thoughts.

1. SITUATION	2. INITIAL THOUGHTS	3. FEELINGS
AFTER DISCUSSION WITH [REDACTED] ABOUT SLEEP, ON THE EFFECTS OF EXCESSIVE COMPETITION USE IN THE EARLY HOURS. DECIDED NOT TO SLEEP THE ENTIRE NIGHT UNTIL ALMOST AWAKE AT THE KEY BOARD USUALLY 3.30 TO 4.30 AM.	IT IS GOING TO BE DIFFICULT TO SLEEP THIS WEEK. ESTABLISHED HABIT.	I AM NOT 100% CONVINCED THAT I NEED MORE SLEEP BUT WANT TO GIVE IT A TRY.
4. OTHER, MORE REALISTIC AND HELPFUL THOUGHTS	5. FEELINGS	6. WHAT DID YOU DO NEXT?
I HAVE FOR THE MOST OF MY TIME AT [REDACTED] BEEN GOING TO BED EARLY. SO IT MAY NOT BE QUITE SO HARD TO JUST SLEEP OFF AT 12 O'CLOCK, INSTEAD OF WHEN MY BRAIN STARTS ITSELF OFF AT 4.30 AM. IT SHOULD NOT BE TOO DIFFICULT. THINGS MIGHT BE I WILL BE Tired AFTER TEN HOURS. FIRSTLY AND SATURDAY WILL BE MORE TESTING.	NOT TO WORRY WHAT I AM THINKING.	FORGOT MYSELF TO SLEEP OFF AT MIDNIGHT. JUST AFTER AND GO TO BED. FEEL OK DURING THE DAY. NO UNPLEASANT WITHDRAWAL SYMPTOMS APPARENT AS YET.

1. SITUATION	2. INITIAL THOUGHTS	3. FEELINGS
Woken up early 4.4am for pain, + effects of cold + chest infection	Yet another night without sleep	Worn out, + tired.
4. OTHER, MORE REALISTIC AND HELPFUL THOUGHTS	5. FEELINGS	6. WHAT DID YOU DO NEXT?
GET UP + GET A DRINK, to stretch my legs etc and help coaching.	Scio from coaching, and sick from scotches.	went to get a drink + some medicine, took it back to bed, when could medicine didn't tried to do relaxation. Did not read for extra medication as I usually would have.

## APPENDIX 20

### Sample feedback letter

Dear XXXX,

First of all thank you for all your help in filling in the sleep diaries and questionnaires for the sleep study during your time at XXXXX. I have now finished analysing the results from everyone who took part and thought you might like some feedback on the progress you made and on the overall findings of the study.

You will find enclosed three graphs which summarise the data collected from the sleep diaries you filled in. Sleep duration refers to the number of hours that you slept each night, wakes after sleep onset means the number of times you woke during the night and found it hard to get back to sleep, and sleep quality refers to the quality of each night's sleep. I didn't do a graph of how long it took you to fall asleep each night because this was not a problem for you. You will see that the graphs are split into five different phases: the time between your pre-treatment appointment and admission to XXXX; the first two weeks on the programme; the two weeks you had back at home; the second two weeks on the programme; and finally, the month between ending the programme and coming back for your follow-up appointment.

We can see from these graphs that you made improvements in all three areas of your sleep: during the follow-up period you were sleeping for more than half an hour each night on average compared with before you came to XXXXX; almost as soon as you came on to the programme, the number of times you were waking during the night decreased; and over the course of the study, your ratings of the quality of your sleep went gradually up. The long dashed lines on two of the graphs show a trend towards the variability in your ratings of sleep duration and quality decreasing, meaning that your sleep pattern was becoming more stable over time.

The questionnaires you filled in also echoed these improvements. By your follow-up appointment you were indicating that you felt more confident in your ability to manage your sleep. Your score on the questionnaire measuring sleep disturbance not only improved, but also placed you in the range for normal sleepers. This was all achieved with you also making a reduction in your night-time medication.

This is a great pattern of results XXXX, and a credit to you in the hard work you put into the programme and thinking about your sleep. I know from the comments you wrote on your final diary that you were observing these changes too. It was also good to hear that you were recognising things that helped your sleep - planning during the day and not getting so much sleep at night. I would imagine that cutting out the daytime naps, pacing and relaxation were important factors too.

Overall, the study showed that most people attending the programme do make some improvements in their sleep, and have more ideas about ways to cope when they cannot sleep, although this varied from person to person. The interviews revealed the importance of a wide range of factors in influencing the quality of peoples' sleep when they have chronic pain. In particular the kind of thoughts people were having about their difficulties in sleeping seemed important.

We plan to present these results to other pain management programmes because at present, very little research has been done on sleep and chronic pain. I am grateful for all your help in taking part and hope that the improvements you made are continuing.

Yours sincerely,

Kate Treves  
Investigator